

Oklahoma State Board of Pharmacy  
2009 New & Revised Rules

Effective 7/01/2009

**TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY  
CHAPTER 1. ADMINISTRATIVE OPERATIONS**

**SUBCHAPTER 5. GENERAL COURSE IN METHOD OF OPERATIONS**

**535:1-5-5.1. Complaint confidentiality**

(a) In order to encourage the public and affected individuals to come forward with complaints regarding registrants and fully share the particulars, the Board will hold all informant or complainant names, addresses or other personal information as confidential and shall not release this information.

(b) The Board shall use all complainant or informant information provided in conducting its investigations. The Board may use this information in cases filed against registrants. ~~However, the confidential information listed in (a) above will be redacted from case files prior to providing the information to the public.~~

(c) Information obtained during an investigation into violations of the Oklahoma Pharmacy Act is not a record as that term is defined in the Oklahoma Open Records Act nor shall such information be subject to subpoena or discovery in any civil or criminal proceeding.

(d) The respondent may acquire information obtained during an investigation, unless the disclosure of such information is otherwise prohibited, except for the investigation report, if the respondent signs a protective order whereby the respondent agrees to use the information solely for the purposes of defense in the Board proceeding and in any appeal there from and agrees not to otherwise disclose the information.

**SUBCHAPTER 7. INDIVIDUAL PROCEEDINGS**

**535:1-7-2. Serving of notices**

(a) All notices or other papers requiring service in an individual proceeding shall be served in one of the following manners:

(1) personally by any person appointed to make service by the Director of the Board and in any manner authorized by the law of this State for the personal service of summonses in proceedings in a state court; or,

(2) by certified or registered mail, ~~mailed by the Director of the Board or his designee addressed to the respondent at the last such post office address provided to as he may have filed with the Board of Pharmacy, or if no such address is in the file, at the by respondent or to respondent's attorney last known post office address.~~

(b) ~~Service of notice shall be complete upon the receipt of the card showing receipt of certified or registered mail or return of the notice by the post office. Such service shall be complete upon the personal service or mailing of the notice or other paper.~~

**535:1-7-4. Failure to appear or failure to comply**

(a) Any respondent ~~defendant or accused~~ who fails to appear as directed, ~~after first having received proper notice,~~ may be determined to have waived his right to present a defense to the charges alleged in the complaint and a suspension, revocation or other disciplinary action may be ordered by the Board if it appears, after having reviewed the evidence, that the violation alleged did in fact occur.

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(b) Failure to comply with the Board's order(s) may result in additional sanctions by the Board.

**535:1-7-5. Subpoenas**

(a) **Issuance; serving.** Subpoenas for the attendance of witnesses, and/or for the furnishing of information required by the Board, and/or for the production of evidence or records of any kind shall be issued by the Director of the Board. Subpoenas shall be served, and a return made in any manner

prescribed by Oklahoma Administrative Procedures Act (APA), et seq.

(b) **Order to compel.** Upon the failure of any person to obey a subpoena, upon the refusal of any witness to be sworn or make an affirmation or to answer a question put to him in the course of the hearing, the Director of the Board may institute appropriate judicial proceedings under the laws of the State for an order to compel compliance with the subpoena or the giving of testimony, as the case may be. Any scheduled ~~The~~ hearing shall proceed, so far as it is possible, but the Board, in its discretion, at any time may continue the proceedings for such time as may be necessary to secure a final ruling in the compliance proceeding.

**535:1-7-7. Final orders**

All final orders in individual proceedings shall be in writing. The final order shall include findings or fact collected and conclusions of law ~~Law~~, separately stated. A copy of the final order will be mailed forthwith to each party.

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## CHAPTER 10. PHARMACISTS; AND INTERNS, PRECEPTORS AND TRAINING AREAS

### SUBCHAPTER 3. PHARMACISTS

#### 535:10-3-4. Uniform pharmacy continuing education

- (a) **Certification.** At the time of annual renewal of registration each pharmacist must certify they have obtained at least 15 clock hours of continuing education credits obtained through satisfactory completion of an accredited program during the previous calendar year.
- (b) **Records.** Proof of continuing education is to be maintained by the individual pharmacist for a period of two years from renewal date (submit to the Board only on request).
- (c) **Verification forms.** Verification forms of attendance and/or completion of continuing education programs shall be obtained and maintained by the pharmacist.
- (d) **Graduate school.** Pharmacists in pharmacy graduate school will be allowed credit for the required fifteen (15) hours continuing education.
- (e) **Military personnel.** Military personnel will not be exempt from the continuing education requirement because of the availability of correspondence courses, etc.
- (f) **Job credit.** No credit for continuing education will be granted for anything directly connected with a pharmacist's job.
- (g) **Journals.** No credit will be allowed for reading, subscribing to or writing articles for various professional and trade journals.
- (h) **Meetings.** Credit for individual meetings will have to be submitted to the Committee on Continuing education for credit by the individual pharmacist.
- (i) **Prior approval.** Prior approval of programs on continuing education shall be obtained by the program sponsor. Each program must be submitted in its entirety, including all materials, in order to be evaluated by the Continuing education Committee. Continuing education programs sponsored by various drug companies will be acceptable, if the programs are continuing education oriented and not promotional or product oriented.
- (j) **Approved programs notice.** Programs approved for credit by the Continuing education Committee and the Board of Pharmacy will be published in the Oklahoma Pharmacist as these programs are approved.
- (k) **Schools Colleges of pharmacy.** The two State colleges ~~schools~~ of pharmacy may review the various continuing education programs and make recommendations to the Continuing education Committee.
- (l) **American Council on Pharmaceutical Education (ACPE).** The Oklahoma Board accepts ACPE approved continuing education (CE) for CE credit.
- (m) **Continuing Education Committee.** The Continuing education Committee will consist of up to six (6) pharmacist members appointed by the Board for a three (3) year minimum term. The committee will meet quarterly or as needed.
- (n) **Live Continuing education recommended.** Pharmacists are encouraged to attain three (3) hours or more of live continuing education (CE) each year as part of the fifteen (15) hours required. Live CE is attained in the presence of other pharmacists with a presenter and the possibility of interaction with a peer group.

### SUBCHAPTER 5. INTERNS, PRECEPTORS AND TRAINING AREAS

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**535:10-5-1.1. Purpose**

(a) The rules of this subchapter define how pharmacy college students or graduates can obtain the experience required of them under the Oklahoma Pharmacy Act Title 59, Section 353 et seq. in order to be eligible for licensure as a pharmacist.

(b) These rules allow individuals to work as an intern when they are continuously actively enrolled and participating in a PharmD in Pharmacy program to earn the practical experience required for licensure as a pharmacist.

(c) The purpose of an intern license is to allow an registrant to gain the required practical experience, under supervision, to become licensed as a pharmacist.

**535:10-5-1.2. Definitions**

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

**'Currently enrolled'** means a student currently enrolled in a college of pharmacy in a PharmD program and attending classes or pro-practice rotation.

**'Faculty preceptor'** means an Oklahoma licensed pharmacist who is an Oklahoma licensed preceptor employed by a ~~school or~~ college of pharmacy to conduct a pro-practice rotation.

**'Foreign pharmacy graduate intern'** means a graduate of a foreign ~~school or~~ college of pharmacy who has verified NABP FPGE certification and has received an Oklahoma intern certificate from the Board.

**'Intern' or 'Registered Intern'** means a student having completed fifty (50) college hours of credit, with an overall average of not less than "C"; currently enrolled and in good standing attending classes in an accredited college of pharmacy PharmD in Pharmacy program currently approved by the Board; or a graduate of an accredited college of pharmacy currently approved by the Board not otherwise eligible for registration as an intern or pharmacist, except as provided in 535:10-7-8 ~~currently enrolled and in good standing or graduate of an accredited school or college of pharmacy approved by the Board~~ who has received an Oklahoma Intern certificate from the Board.

**'Intern duties'** means those duties that may be performed by a licensed Intern while working in a licensed training area under the supervision of a preceptor. The licensed Intern may do any of the functions of a Pharmacist for which they have been trained with the exception of supervising technicians or any other exceptions noted in Title 535. All intern duties must be performed in compliance with the rules of 535:10-5 and this Title.

**'Intern hours'** means the hours a licensed intern must acquire in order to be eligible for licensure as a pharmacist.

**'Pro-practice' or 'college or school pro-practice'** means a structured advance practice rotation administered by the faculty of a college ~~or school~~ of pharmacy.

**535:10-5-3. Intern requirements; licenses**

(a) A registered intern shall be defined as a student having completed fifty (50) college hours of credit, with an overall average of not less than "C", currently enrolled and attending classes and in good standing in an accredited ~~school or~~ college of pharmacy in a PharmD in Pharmacy program, or

(b) a graduate of an accredited ~~school or~~ college of pharmacy not otherwise eligible for

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registration as an intern or pharmacist, except as provided in 535:10-7-8.

(1) The Board of Pharmacy shall be notified by the Pharmacy ~~Colleges~~ Schools in Oklahoma

(A) when a student is not continuously enrolled in a college of pharmacy school in an accredited Pharmacy program; or,

(B) when a pharmacy ~~student's~~ student is not in good standing for overall grade point average is less than "C";

~~(2) (C) Then When an intern license or registration is not continuously enrolled and in good standing, as defined in 535:10-5-3 (1), the certificate of internship is automatically void, and the~~ The intern shall return such license to the Board.

(2) Such intern may apply for a new intern license when the Board is notified by the college of pharmacy school that the applicant is in good standing in pharmacy school, in a PharmD in Pharmacy program provided the provisions of these regulations have not been violated by the intern.

(3) An intern shall notify the Board when requesting the transfer of intern hours to another state of any intent not to return to Oklahoma; or, within ten (10) days of becoming licensed as a pharmacist in another state.

(4) An intern certificate becomes void five (5) years after date of issuance or at such other date as set by the Board.

#### 535:10-5-4. Intern practice requirements

(a) **Supervision requirement.** An intern may practice in an approved training area only under the immediate visual supervision of a preceptor, except as described in 535:10-5-4-(a) (3). See also 535:10-5-2.

(1) A preceptor may supervise only one intern at a time.

(2) A ratio of one (1) faculty preceptor with up to two (2) interns will be allowed in a pro-practice rotation.

(3) Non-dispensing pro-practice rotations are to be supervised by a preceptor, but immediate visual supervision is not required.

(b) **Professional Conduct.** Interns will be held accountable to the rules and violations of professional conduct. The professional conduct rules for interns will be the same as required by 535:10-3-1.1 and 535:10-3-1.2 for pharmacists.

(c) **Employment notification.** All licensed pharmacy interns shall notify the Board of Pharmacy, in writing, of the place of their non-college practice within ten (10) days of going to work and/or termination of this practice location. The pro-practice employment location notification will be the responsibility of the college ~~or school~~ of pharmacy.

#### 535:10-5-5. Intern credit hours; computation

(a) **Intern pro-practice hours.** A pharmacy intern pursuing a PharmD degree in an accredited ~~school or~~ college of pharmacy may obtain up to 1,500 intern hours while completing the degree.

(1) Pro-practice hours will be obtained through a board approved ~~school or~~ college of pharmacy professional practice program.

(2) Documentation of pro-practice hours shall be provided to the Board by the ~~school or~~ college of pharmacy on a Board approved form.

(b) **Intern non-college practice hours.** Non-college practice hours will be a learning

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experience, earned in a pharmacy that is licensed as a training area, under the supervision of licensed preceptor. The preceptor will send a "Preceptor's Intern Progress Report" to the Board (on a form furnished by the Board) every 240 hours or upon termination of the intern.

(c) **Computation of hours.** Computation of hours for credit for an intern shall be on the basis of forty (40) hours for one (1) calendar week's work. Hours gained in excess of forty (40) hours in one calendar week shall not be credited.

**535:10-5-9. Training area requirements**

(a) **Pharmacies.** Any pharmacy desiring approval for the training of interns shall make application to the Board of Pharmacy on a form supplied by the Board. The Board will consider the requirements and qualifications listed in 535:25-3 at a minimum. A pharmacy approved as a training area shall conspicuously display ~~it's~~ its training area certificate in the pharmacy, and be subject to the following provisions:

(1) Such pharmacy shall be subject to inspection by the Board.

(2) Such pharmacy shall agree to furnish the necessary preceptor(s) under whose supervision the intern will be allowed to perform the duties outlined in this Subchapter. The number of interns practicing in a training area is limited to the number of preceptors present and on duty in a training area.

(3) No pharmacy under probation or suspension by the Board shall be approved as a training area. A pharmacy will not be able to continue as a training area under the above conditions. A pharmacy must apply for a new training area certificate and be approved by the Board after completion of probation and/or suspension.

(4) All training areas shall submit reports as required by the Board.

(5) The Board shall set the training area original certification fee.

(6) All training areas shall renew their certification for a fee set by the Board.

(7) Training area renewal certification will be effective January 1, 2000 and expire December 31, 2002, 2005 and every three years thereafter.

(b) **Unique or specific training areas.** Any Oklahoma college ~~or school~~ of pharmacy may apply to the Board for approval of a specific or unique training area. This training area shall be subject to Subsection (a) (1), (2), (4) and (5) of this Section.

(c) **Changes.** Changes of pharmacy location, name or ownership shall require a new training area certificate.

**535:10-5-13. Intern file destruction**

(a) An intern file may be destroyed if an intern:

(1) is dropped from a college of pharmacy school;

(2) becomes a licensed pharmacist in any state; or transfers by reciprocity or score transfer to another state; or,

(3) license expires.

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**SUBCHAPTER 7. PHARMACIST LICENSURE**

**535:10-7-8. Foreign pharmacy graduate licensure applicants**

(a) Foreign pharmacy graduate applicants shall meet the requirements set forth in 535:10-7-4, 535:25 and this Subchapter and Title.

(b) Foreign pharmacy graduate applicants, as defined in 535:10-7-2 shall:

- (1) First, submit a copy of applicant's valid NABP FPGE Certificate to the Board;
- (2) second, apply and be approved for an Oklahoma intern certificate as required by 535:10-5-2; and,
- (3) third, complete 1000 hours of internship in Oklahoma within 12 months of licensure as an Oklahoma intern.

(A) The foreign pharmacy graduate intern and the preceptor shall satisfactorily report these hours on forms supplied by the Board.

(B) The foreign pharmacy graduate intern is subject to all Board rules.

(c) Upon satisfactorily completing the requirements of this section, a foreign pharmacy graduate may make application for ~~(1) the NAPLEX (licensure by examination) as set forth in 535:10-7-5;~~ ~~or,~~

~~(2) Reciprocity as set forth in 535:10-7-6; or,~~

~~(3) Score transfer as set forth in 535:10-7-7~~

(d) Foreign pharmacy graduates applicants may apply for licensure by reciprocity once they have met the following:

(1) Successfully complete the NABP FPGE certificate, and submit a copy to the Board;

(2) Have passed the NAPLEX Examination; and,

(3) Have met the requirements in 535:10-7-6.

**SUBCHAPTER 11. PHARMACIST ADMINISTRATION OF IMMUNIZATIONS**

**535:10-11-3. D.Ph. administering of immunization requirements**

(a) A D.Ph. must have completed an approved training course and received registration for immunizations with the Board as stated in 535:10-11-4 prior to administering immunizations.

(b) A D.Ph. shall administer immunizations ~~only on the patient-specific prescription order of a~~ prescribing practitioner.

(c) The Board will maintain a register of those pharmacists who have been approved for immunizations.

(d) A D.Ph. with immunization registration must maintain ongoing competency through required training, e.g. CPR and continuing education.

**535:10-11-5. D.Ph. training requirements for administration of immunizations**

(a) The following is a list of approved pharmacist training programs for administration of immunizations:

(1) Programs that include training in immunizations offered by the two state colleges of pharmacy:

(A) Southwestern Oklahoma State University (SWOSU) College of Pharmacy

(B) University of Oklahoma (OU) College of Pharmacy

(2) Immunization programs approved by the Accreditation Council for Pharmacy

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~~American Council on Pharmaceutical Education (ACPE).~~

(3) Immunization programs offered by the American Pharmaceutical Association (APHA).

(4) Immunization programs offered by the National Community Pharmacy Association (NCPA).

(5) Immunization programs offered by the American Society of Health System Pharmacists (ASHP).

(b) Each D.Ph must have successfully completed one of these training courses in immunization prior to registering with the Board or administering immunizations prescribed by an Oklahoma licensed prescribing practitioner.

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## CHAPTER 15. PHARMACIES

### SUBCHAPTER 3. PHARMACIES

#### **535:15-3-4.1. Pharmacy licensing requirement**

(a) Every pharmacy conducting ~~interstate and/or~~ intrastate transactions in Oklahoma ~~must~~ shall be licensed as required under Title 59, O.S., Section 353.18(A). Every pharmacy shall also be licensed as required by Title 59 O.S. Section 353.18(A) if Oklahoma is the state from which it or to which it delivers, distributes, or dispenses or offers to sale, deliver, distribute, or dispense dangerous drugs, medicines, chemicals or poisons for the treatment or prevention of diseases, excluding agricultural chemicals and drugs.

(b) Every pharmacy shall list the corporate registered agent and address as required on their new and/or renewal application.

(c) Every applicant for pharmacy license issued under Title 59 O.S. Section 353.18 shall fully and completely disclose ownership as required by the Board on their new and/or renewal application.

#### **535:15-3-9. Non-resident pharmacies**

(a) **Definitions.** “**Non-resident pharmacy**” means a pharmacy, not located in Oklahoma, that transacts or does business in Oklahoma by soliciting, receiving, dispensing, and/or delivering prescription medications and devices to Oklahoma residents.

(b) **Licensing requirements.** A non-resident pharmacy shall:

- (1) make application and receive an annual non-resident pharmacy license at a fee set by the Board;
- (2) maintain in good standing a pharmacy license in its resident state; and,
- (3) comply with the Oklahoma Secretary of State requirements for conducting business in this state.

(c) **Laws and regulations.** Oklahoma pharmacy laws and regulations shall apply to the practice of pharmacy for the Oklahoma portion of the nonresident pharmacy's practice or operation.

(1) The pharmacist manager (pharmacist in charge (PIC)) and all other pharmacists performing pharmacist-only functions in Oklahoma licensed non-resident pharmacies must be currently licensed in the state in which they are practicing.

(2) The pharmacist manager (PIC) and/or pharmacy owner(s), or partners, or corporate officer(s) shall be responsible for compliance with Oklahoma laws and regulations pertaining to the provisions of receiving, dispensing, and/or delivering prescription medications and devices to Oklahoma residents.

(3) The requirement of 535:15-3-9 (c) and (e) shall apply only to the extent that such requirements are consistent with the laws and rules of the pharmacy's resident state.

(d) **Inspections.** Non-resident pharmacies are subject to inspection as follows:

- (1) Oklahoma pharmacy inspectors may conduct on-site periodic routine inspections during reasonable business hours; or
- (2) The Oklahoma Board may request copies of the resident state Board of Pharmacy's periodic routine inspection reports.

(e) **Records.** Prescription records documenting prescriptions delivered and distributed to Oklahoma residents shall be identifiable, readily retrievable and available for Board review.

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- (1) Records must be maintained for not less than five years.
- (2) Patient records shall comply with 535:15-3-14.
- (3) Schedule II, III, and IV prescription records should be sent to the Oklahoma Control Reporting Schedule Two Abuse Reduction (OSTAR) program as set out in Title 63 of the Oklahoma Statutes.

(f) **Counseling services.** Non-resident pharmacies shall provide an accessible toll-free telephone counseling service with a licensed pharmacist for patient drug inquiries during regular working hours. The counseling provided shall comply with the pharmaceutical care requirements listed in OAC 535:10-9.

(g) **Prescription integrity.** A pharmacy shall not increase the quantity of a prescription without the authorization of the prescriber.

#### 535:15-3-10. Inventory

(a) **Change of ownership or pharmacy manager inventory.** When changing the owner or pharmacy manager, a controlled drug inventory must be taken and sent to the Board within ten (10) days. (It is recommended that both the out-going and in-coming managers sign the inventory). The inventory must indicate the new manager's name and registration number. The inventory should indicate the former manager's name, registration number and current employment, if known.

(b) **Inventory at renewal.** An inventory of all controlled dangerous substances (CDS) must be taken between May 1 and July 1 of each year. A copy of this inventory will be included with the pharmacy renewal application.

(c) **Board requested inventory.** In the case of suspected loss, theft, and/or diversion, a pharmacy may be requested by the Board to conduct an inventory (all, or in part), within ten (10) days and submit a copy to the Board.

#### 535:15-3-13. Pharmacist's responsibility in a pharmacy

(a) **Access to drugs.** Only a pharmacist shall be responsible for control and distribution of all drugs.

(1) Only the pharmacist shall be permitted to unlock the pharmacy area or any additional storage areas for dangerous drugs, except in extreme emergency.

(2) An extreme emergency shall be in case of fire, water leak, electrical failure, public disaster or other catastrophe whereby the public is better served by overlooking the safety/security restrictions on drugs.

(3) Prescription medications shall not be left outside the prescription area when the pharmacist is not in attendance.

(b) **Professional judgement.** A pharmacist is required to exercise sound professional judgement with respect to the legitimacy of a prescription. The law does not require a pharmacist to dispense a prescription if the pharmacist doubts its origin or if he believes that the prescription may not have been issued for a legitimate medical purpose.

(c) **Legitimate purpose.** The pharmacy or pharmacist shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner acting in the usual course of the practitioner's professional practice.

(d) **Valid patient practitioner relationship.** The pharmacy or pharmacist shall not dispense a

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prescription drug if the pharmacist knows or should have known that the prescription was issued solely on the basis of an internet-based questionnaire, an internet-based consultation, or a telephonic consultation without a valid preexisting patient-practitioner relationship.

(e) **Valid prescription drugs.** Only those prescription drugs legal to sell in the United States shall be dispensed. (e.g. FDA approved prescription drugs, or legally compounded prescription drugs, or drugs in a drug-testing protocol, or other legal prescription drugs.)

## SUBCHAPTER 6. HOSPITAL DRUG ROOMS

### 535:15-6-4. Staffing requirements

(a) The PIC shall be assisted by a sufficient number of additional pharmacists (D.Ph.s) to operate such a drug room competently, safely and adequately to meet the needs of the patients of the hospital facility.

(b) Each hospital drug room shall have oversight by a PIC who shall be responsible for certifying that the drug room meets the requirements of the Oklahoma Pharmacy Act and the rules of this Title. The PIC shall notify the Board, in writing, within 10 days of any change of employment.

(c) A drug room supervisor must be assigned as designated in the rules of the Oklahoma Department of Health under OAC 310:667-21-2(c) et seq.

### 535:15-6-11. Administration of drugs to patients

(a) **General provisions.** Drugs shall be administered at a hospital facility in accordance with the policies and procedures of that facility.

(b) **Self-Administration.** Self-administration of drugs by patients shall be permitted per hospital policy only when specifically authorized by the prescribing ALI practitioner per hospital policy, provided the drugs to be self administered have been identified by a licensed pharmacist or ALI practitioner.

(c) **Administration only.** The drugs supplied or provided from a drug room shall be for administration only to patients of the hospital. No drugs may be provided to employees nor to individuals who are not patients of the hospital.

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## SUBCHAPTER 10. GOOD COMPOUNDING PRACTICES

### PART 1. GOOD COMPOUNDING PRACTICES FOR NON-STERILE PRODUCTS

#### 535:15-10-2. Definitions

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

**'Beyond-Use Date (BUD)'** means the date and time, as appropriate, after which a compounded preparation is not to be used and is determined from the date the preparation is compounded.

**'Biological Safety Cabinet (BSC)'** means a ventilated cabinet for hazardous drugs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection meeting USP standards.

**'Compounder'** means a compounder is a pharmacist or anyone compounding under the direct supervision of a pharmacist pursuant to a prescription order by a licensed prescriber.

**'Compounding'** means the preparation, mixing, assembling, packaging, and labeling of a drug or device ~~as the result of~~ in accordance with a licensed practitioner's prescription drug order ~~or~~ under an initiative based on the Practitioner/Patient/Pharmacist/Compounder relationship in the course of professional practice.

(A) Compounding may be for the purpose of, or as an incident to, research, teaching, or chemical analysis.

(B) Compounding includes the preparation of Drugs or Devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(C) Reconstitution of commercial products is not considered compounding for the purposes of this subchapter.

(D) Manipulation of commercial available products according to or beyond the manufacturer's instructions or copying commercially products for the reason of non-availability or component specifications would be considered compounding as pertaining to a practitioner / patient / compounder relationship.

**'Component'** means any ingredient used in the compounding of a drug product, including those that may not appear on the labeling of such a product.

**'Hazardous drug'** means any drug listed as such by NIOSH and/or any drug identified by at least one of the following six criteria: 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.

**'Inordinate Amount'** means an amount of compounded drug that exceeds the amount a pharmacy anticipates may be used or dispensed before the BUD of the compounded drug and/or is unreasonable considering the intended use of the compounded drug.

**'Isolator'** means a device that is sealed or is supplied with air through a microbially retentive filtration system (HEPA minimum) and may be reproducibly decontaminated.

**'Labeling'** means all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term 'label' designates that part of the

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labeling on the immediate container.

**'Manufacturing'** 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 and includes any packaging or repackaging of the substance(s) or labeling or re-labeling of its container, ~~and~~ for the promotion and marketing of such drugs or devices. Manufacturing also includes any preparation of a drug or device that is given or sold for resale by pharmacies, practitioners, or other persons. The distribution of inordinate amounts of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing.

**'Personal Protective Equipment (PPE)'** means items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.

**'Pharmacy Generated Products' or '(PGP)'** means a medical product that is prepared, packaged and labeled in a pharmacy that can be sold by the pharmacy without a prescription.

**'Preparation'** means an article compounded in a licensed pharmacy pursuant to the order of a licensed prescriber.

**'Product'** means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

**'USP'** means 'United States Pharmacopeia'

### 535:15-10-3. Pharmacist responsibilities

(a) All Pharmacists who engage in drug compounding, shall be proficient in compounding and should continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature.

(b) Every pharmacist engaging in drug compounding shall be familiar with all details of ~~Good~~ USP Compounding Practices Standards and should be familiar with ~~FDAMA-related~~ patent regulations.

(c) The pharmacist has the responsibility to:

(1) ensure the validity of all prescriptions

~~(1)~~ (2) certify all prescriptions.

~~(2)~~ (3) approve or reject all components, drug product containers, closures, in-process materials, and labeling.

(4) ensure preparations are of acceptable strength, quality, and purity.

(5) verify all critical processes to ensure that procedures will consistently result in the expected qualities in the finished preparation.

~~(3)~~ (6) prepare and review all compounding records to assure ensure that no errors have occurred in the compounding process.

(7) ensure appropriate stability evaluation is performed or determined from the literature for establishing reliable beyond-use dating.

~~(4)~~ (8) assure ensure the proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice; and,

~~(5)~~ (9) assure ensure only authorized personnel shall be in the immediate vicinity of the drug compounding operation.

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(10) perform final check of preparations prior to their release from the pharmacy.

(A) A check for compounding accuracy must ensure accuracy of the label and volumes or quantities of all drugs and solutions

(B) A visual examination procedure must ensure:

(i) Comparison with original order for initial dispensing

(ii) Accuracy of calculations

(iii) Use of proper solutions, additives and equipment

(iv) Labels are complete

(v) Proper assignment of beyond use date and time

(vi) Integrity of the container, including visual defects

(vii) Proper storage

(viii) Absence of particulate matter, precipitates, turbidity, discoloration, evidence of contamination or other signs that the preparation should not be used

(C) The pharmacist shall reject and destroy all preparations that do not pass the final examination.

(D) Pharmacists shall document final preparation examinations prior to releasing the Compounded Sterile Preparations from the pharmacy.

(d) The pharmacist-in-charge has the responsibility to ensure that all compounders who compound pharmaceuticals meet all requirements for training, testing and education set forth in these regulations and contained in the regulations set forth in USP standards.

(1) Competency shall be demonstrated prior to preparing any products for patient use, and

(2) Whenever the quality assurance program yields unacceptable results, and

(3) Whenever unacceptable or questionable techniques are observed, and

(4) Evaluated at least annually.

(e) Pharmacist requirements. Any pharmacist in charge who performs or supervises the preparation of compounded medications shall:

(1) Have available written policies and procedures for all steps in the compounding of preparations. In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, quality assurance, expiration dating, and other procedures as needed.

(2) Certify that all participating pharmacists and pharmacy technicians have completed training and testing program in product preparation. Documentation of training and testing shall be available for review.

(3) Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians.

(f) Staff will be trained and evaluated according as follows:

(1) Training is required for any individual who prepares compounded products. This training must be completed before the employee is allowed to prepare compounded products.

(2) Training may consist of any combination of didactic and experiential methods which must convey proper technique, infection control procedures, etc. required by USP standards.

(3) A written test shall be administered and passed based on the material referenced above upon initial hire or prior to assignment to prepare compounded products.

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(4) Testing will be conducted annually for every employee involved in product preparation. Compounding personnel who fail written tests shall be immediately reinstructed and reevaluated by expert compounding personnel to ensure correction of all practice deficiencies.

(5) An 'Individual Training Record' shall be maintained for every employee involved in sterile product preparation.

(6) Nothing in these regulations shall prohibit a licensed student pharmacy intern engaged in experiential classes from assisting a properly qualified pharmacist in preparing sterile products under that pharmacist's direct supervision.

(7) Complete documentation by a pharmacist of training and testing shall be available for inspection.

(g) Pharmacy technician requirements. Pharmacy technicians participating in the preparation of compounded products shall have completed a pharmacist supervised training and testing program in product preparation. Completed documentation by a pharmacist of training and testing shall be available for inspection.

**535:15-10-4. Drug compounding facilities**

(a) Pharmacies engaging in compounding shall have a specifically designated and adequate space for the orderly compounding of prescriptions, including the placement and storage of equipment and materials.

(b) The aseptic processing for sterile products shall be in an area separate and distinct from the area used for the compounding of non-sterile drug products.

(c) The area(s) used for the compounding of drugs shall be maintained in a good state of repair. These area(s) shall also be maintained in a clean and sanitary condition. Adequate washing facilities are to be provided and sewage, trash and other refuse in the compounding area is to be disposed of in a safe, sanitary, and timely manner.

(d) Hazardous drugs shall be prepared within a certified Class II, Type A (exhaust may be discharged to the outdoors) or Class II, Type B (exhaust may be discharged to the outdoors) laminar flow biological safety cabinet. All new construction, and those undergoing renovation requiring the moving of existing hoods used in the preparation of cytotoxic drugs, shall exhaust the hood to the outdoors, unless the Board of Pharmacy grants an exception. Hazardous drug compounding shall have negative pressure to adjacent positive pressure areas, thus providing inward airflow to contain any airborne drug. All vented cabinets shall be vented through HEPA filtration, preferably to outside air or through use of suitable technology or equipment. Ventilation exhaust shall be placed as not to reenter the facility at any point.

(d) ~~(e)~~ Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored as directed by the manufacturer, or according to USP monograph requirements, in a clean, dry area, under appropriate temperature conditions (controlled room temperature, refrigerator, or freezer in adequately labeled containers). Bulk drugs shall also be stored such that they are protected from contamination.

(e) ~~(f)~~ Adequate lighting and ventilation shall be provided in all compounding areas.

(f) ~~(g)~~ Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product.

~~(g) These area(s) used for compounding shall be maintained in a clean and sanitary condition.~~

(h) Purified water must be used for compounding non-sterile drug preparations when

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formulations indicate the inclusion of water.

~~(h) If parenteral products are being compounded, the rules in Subchapter 9 must be met.~~

**535:15-10-5. Compounding equipment**

(a) Equipment used in the compounding of drug products shall be of appropriate design and capacity as well as suitably located to facilitate operations for its intended use, cleaning and maintenance.

(b) Compounding equipment shall be of suitable composition so the surfaces that contact components shall ~~not~~ neither be reactive, additive nor absorptive ~~so as to alter, therefore not affecting or altering~~ the purity of the ~~product~~ preparation compounded.

(c) Equipment and utensils used for compounding shall be thoroughly cleaned and ~~sanitized~~ immediately prior to promptly after every use to prevent contamination and ~~(d) Equipment and utensils~~ must be stored in a manner to protect them from contamination.

(d) Defective equipment shall be clearly labeled as such.

(e) Automated, mechanical, electronic, limited commercial scale manufacturing or testing equipment, and other types of equipment may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated ~~(if as necessary)~~, or checked to ensure proper performance.

~~(f) Immediately prior to the initiation of compounding operations, the equipment and utensils must be inspected by the pharmacist and determined to be suitable for use.~~

~~(g) (f)~~ When drug products with special precautions (antibiotics, and hazardous materials and radiopharmaceuticals) are involved, appropriate measures must be utilized in order to prevent cross-contamination and proper disposal procedures must be followed. These measures include either the dedication of equipment for such operations or the meticulous cleaning of equipment prior to its use for the preparation of other drugs. Equipment dedicated for specific use (i.e. penicillin) shall be clearly designated as such.

**535:15-10-6. Component selection requirements**

(a) ~~The Pharmacist-pharmacist~~ shall first attempt to use USP-NF drug substances and inactive components ~~for compounding~~ that have been made in an FDA ~~inspected~~ registered facility.

(b) If components are not obtainable from an FDA ~~inspected~~ registered facility or if the FDA and/or the company cannot document FDA ~~inspection~~ registration, pharmacists compounding prescriptions shall use their professional judgment in first receiving, storing or using drug components that meet official compendia requirements or another high quality source.

(c) If components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, American Chemical Society-certified, or Food Chemicals Codex grade may be used.

(d) Components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first.

**535:15-10-7. Control of drug product containers**

(a) Drug product containers and closures shall be handled and stored in a manner to prevent contamination and to permit inspection and cleaning of the work area.

(b) Containers and closures shall be of suitable material as to not alter the compounded drug as to quality, strength or purity of the compounded preparation.

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**535:15-10-8. Drug compounding controls**

(a) There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality and purity they purport ~~or are represented to have possess.~~ These procedures should be available in either written form or electronically stored with printable documentation.

(b) The objective of the documentation is to allow another compounder to reproduce an equivalent prescription at a future date.

~~(b)~~ (c) Procedures shall include a listing of the components, their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. ~~(e) In addition, All~~ all equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug shall be listed.

(d) These written procedures shall be followed in the execution of the compounding procedure and are designed to enable a compounder, whenever, necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation.

(e) Components shall be accurately weighed, measured, ~~or~~ and subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight and measure is correct as stated in the written compounding procedures.

(f) Written procedures shall be established and followed that describe the tests or examinations to be conducted on the product compounded (e.g., degree of weight variation among capsules) to assure reasonable uniformity and integrity of compounded drug ~~products~~ preparations. Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall contain not less than 90% and not more than 110% of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less than 90% and not more than 110% of the theoretically calculated weight or volume per unit of the preparation.

(1) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. ~~(2) Such control~~ These procedures shall include, but are not limited to, the following (where appropriate):

(A) Capsule weight variation to ensure that each unit shall be not less than 90% and not more than 110% of the theoretically calculated weight for each unit;

(B) Adequacy of mixing to assure uniformity and homogeneity;

(C) Clarity, completeness or pH of solutions.

(2) The compounder shall label any excess compounded products so as to reference them to the formula used, the assigned batch number, and beyond use date based on the compounder's appropriate testing, published data, or USP-NF standard.

~~(g) Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall include validation of any sterilization process.~~

~~(h) Beyond use dates and storage requirements (e.g., refrigeration) should be established. The U.S.P. NF Guidelines should be used.~~

(g) Material safety data sheet (MSDS) files should be easily accessible.

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(h) General requirements:

(1) Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product is generally prohibited unless patient therapy is compromised.

(2) However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is different from an FDA-approved drug that is commercially available based on documentation provided by the prescribing physician of a patient specific medical need (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available.

(A) The unavailability of such drug product must be documented prior to compounding.

(B) This or similar documentation must be available when requested by the Board.

(3) Except for those products where stability prohibits advanced compounding, all products dispensed by the pharmacy shall be in a form ready for administration, except in health care facilities where medications may be provided as demanded by policies and procedures.

**535:15-10-8.1. Transfer of compounded prescriptions**

(a) If a patient requests a transfer of their prescription, a copy of the original prescription shall be transmitted upon the request of the receiving pharmacist.

(b) The information included in the transfer of the prescription shall include:

(1) Active ingredient(s).

(2) Concentration.

(3) Dosage Form e.g. capsule, cream, suspension, injectable, etc.

(4) Route of delivery e.g. oral, injectable, topical, vaginal, etc.

(5) Delivery mechanism e.g. topical, transdermal, immediate release, sublingual, etc.

(6) Dosing Duration e.g. Q12H, Q24H, Q72H, etc.

(7) Details about the compounding procedure must be reasonably available from the transferring pharmacy.

**535:15-10-8.2. Beyond-use dating**

(a) Pharmacies engaging in compounding shall assign every compounded preparation an appropriate beyond-use date.

(b) Beyond-use dates may be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.

(c) BUD dates are to be assigned conservatively, and should be based on the following USP-NF standards:

(1) For Non-aqueous liquids and solid formulations

(A) Where the manufactured drug product is the source of active Ingredient – The beyond-use date is not later than 25% of the time remaining until the product's expiration date or 6 months, whichever is earlier.

(B) Where a USP of NF substance is the source of active ingredient – the beyond-use date is not later than 6 months for

(i) Water-containing formulations (prepared from ingredients in solid form) – the beyond-use date is not later than 14 days for liquid preparations when

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stored at cold temperatures between 2° and 8°C (36° and 46° F).

(ii) All other formulations – The beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier.

(2) The USP-NF standards listed above may be exceeded when there is supporting scientific stability information that is directly applicable to the specific preparation (i.e., the same drug concentration range, pH, excipients, vehicle, water content, etc.)

(3) Information to be considered when assigning a beyond-use date includes chemical, physical and microbiological stability; nature of the drug, its chemical degradation mechanism, the container in which it is packaged, expected storage conditions, and the intended duration of therapy.

### **535:15-10-9. Labeling**

(a) If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in ~~a container~~, and stored in another container) the new container shall be identified with the:

- (1) Component name,
- (2) Lot and ~~expiration date~~ BUD if available,
- (3) Strength and/or concentration, and;
- (4) Weight or measure

(b) Products prepared in anticipation of a prescription prior to receiving a valid prescription should not be an inordinate amount.

(1) A regularly used amount should be prepared based on a history of prescriptions filled by the pharmacy.

(2) These products shall be labeled or documentation referenced with the:

- (A) Complete list of ingredients or preparation name and reference,
- (B) Preparation date,
- (C) Assigned beyond-use date:
  - (i) Based on published data, or;
  - (ii) Appropriate testing, or;
  - (iii) USP-NF standards.

(D) Specific storage ~~under~~ conditions dictated by its composition and stability e.g., in a clean, dry place or in the refrigerator shall be specified (refrigerator, freezer etc), except where clean dry area is dictated, and;

(E) Batch or lot number.

(c) Upon the completion of the drug preparation operation, the pharmacist shall examine the product for correct labeling.

(d) The containers and closures shall be of suitable material so as not to alter the quality, strength, or purity of the compounded drug.

(e) The outpatient prescription label shall contain the following:

- (1) Patient name,
- (2) Prescriber's name,
- (3) Name & address of pharmacy,
- (4) Directions for use,
- (5) Date filled,
- (6) Beyond use date & storage (may be auxiliary labels), and;

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(7) An appropriate designation that this is a compounded prescription, such as 'Compounded Rx'.

**535:15-10-10. Records and reports**

(a) Any procedures or other records required to comply with USP Compounding Standards Good Compounding Practices shall be retained for the same period of time as required for retention of prescription records; and copies of such records, shall be readily available for authorized inspection.

~~(b) All records required to be retained under Good Compounding Practices, or copies of such records, shall be readily available for authorized inspection.~~

~~(e)~~ (b) Computer information and the hard copy of the prescription should indicate that the prescription is to be compounded.

~~(d)~~ (c) Adequate records must be kept of controlled dangerous substances (Scheduled drugs) used in compounding.

**535:15-10-11. Pharmacy generated product requirements**

(a) A Pharmacy Generated Product (PGP) ~~may be~~ if prepared from RX Only drugs, ~~not to~~ may not exceed recommended OTC strengths and doses.

(b) PGP will be labeled properly and will be sold with the public's health and welfare in mind.

(c) Compounded PGP's are to be sold directly to the consumer after professional interaction or consultation with the health care provider and the consumer.

(d) A PGP cannot be bulk compounded to sell to a second entity for resale. This would require a manufacturer's license.

**535:15-10-12. Compounding for a prescriber's office use**

(a) Pharmacies engaging in compounding may prepare compounded drug ~~products~~ preparations for a licensed prescriber's office use.

(b) An order by the licensed prescriber indicating the formula and quantity ordered will be filed in the pharmacy.

(c) The ~~product~~ preparation is to be administered in the office and not dispensed to the patient. The preparation label should state 'for office use only-not for resale'.

(d) An invoice shall be kept on file by the pharmacy. This invoice shall include, but not be limited to, the name and address of purchaser, quantity sold, drug description, price, and date of transaction. These invoices must be readily available for inspection. A drug supplier permit is required per OAC 535:15-7.

~~(d)~~ (e) A record of the compounded drug ~~product~~ may be kept as a prescription record in the pharmacy computer and ~~(e)~~ a label may be generated and a number assigned by the pharmacy computer for the compounded drug ~~product~~.

(f) Under Oklahoma Bureau of Narcotics rules [475:30-1-3 (b) et seq.], a prescription for controlled dangerous substances cannot be filled 'for office or medical bag use'.

(g) Compounded preparations may not be given or sold for resale by practitioners or other persons.

**535:15-10-13. Compounding veterinarian products**

(a) Prescriptions for animals may be compounded based on an order or prescription from a

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- licensed prescriber. Compounding for office use for administration by veterinarians is allowed.
- (b) These prescriptions are to be handled and filled the same as the human prescriptions.
- (c) The preparation is to be administered by a veterinarian and not dispensed to the patient. The preparation label should state 'for office use only-not for resale'.
- (d) Caution should be taken as to not violate federal patent laws by duplicating an available product in inordinate quantities.
- (e) An invoice shall be kept on file by the pharmacy. This invoice shall include, but not be limited to, the name and address of purchaser, quantity sold, drug description, price, and date of transaction. These invoices must be readily available for inspection. A drug supplier permit is required per OAC 535:15-7.
- (f) Under Oklahoma Bureau of Narcotics rules [475:30-1-3 (b) et seq.], a prescription for controlled dangerous substances cannot be filled 'for office or medical bag use'.
- (g) Compounding with bulk chemicals for food-producing animals is not permitted.

**535:15-10-14. Compounding of non-sterile hazardous drugs**

Pharmacies engaging in compounding of hazardous drugs shall be responsible for meeting the following criteria:

- (1) Non-sterile hazardous drugs shall include the NIOSH list of hazardous drugs as well as any individual products named per each individual pharmacy by referencing MSDS sheets or any other reference relating to above definition.
- (2) Exposure control shall begin when hazardous drugs enter the facility. The PIC shall be responsible to confirm that medical products have labeling on the outer container that can be understood by all workers who will be separating hazardous from nonhazardous drugs.
- (3) All employees must wear PPE when opening containers to unpack hazardous drugs. Employees must also wear chemotherapy gloves to prevent contamination when transporting the drug to the work area.
- (4) Hazardous drugs must be stored separately from other drugs, as recommended by current ASHP guidelines on handling hazardous drugs. Hazardous drugs must be stored and transported in closed containers that minimize the risk of breakage.
- (5) Pharmacies and pharmacist shall make sure the storage area has sufficient general exhaust ventilation to dilute and remove any airborne contaminants. Use a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. Do not use a ventilated cabinet that recirculates air inside the cabinet or exhausts air back into the room environment unless the hazardous drug(s) in use will not volatilize while they are being handled or after they are captured by the HEPA filter.
- (6) Staff should be fully trained and procedures established for their particular equipment and unique workplace setting.
- (7) All staff shall wear PPE while working with hazardous drugs.
- (8) Mix, prepare, and otherwise manipulate, count, crush, compound powders, or pour liquid hazardous drugs inside a ventilated cabinet designed to prevent hazardous drugs from being released into the work environment.
- (9) Do not use supplemental engineering or process controls (such as needleless

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systems, glove bags and closed-system drug transfer devices) as a substitution for ventilated cabinets, even though such controls may reduce the potential for exposure when preparing and administering hazardous drugs.

(10) Use a high-efficiency particulate air filter (HEPA filter) for the exhaust from these controls.

(11) When drug preparation is complete, seal the final product in a plastic bag or other sealable container for transport before taking it out of the ventilated cabinet.

(12) Wash hands with soap and water immediately before donning and after removing gloves.

(13) Develop a written safety plan for all routine maintenance activities performed on equipment that could be contaminated with hazardous drugs.

(14) Manage hazardous drug spills according to policies and procedures for each workplace according to size of spill, possible spreading etc. Locate spill kits and other cleanup materials in the immediate area where exposures may occur.

(15) Consider a medical surveillance program or allow workers to have routine medical care.

#### **535:15-10-15. Compounding of non-sterile radiopharmaceuticals**

(a) The unique circumstances and requirements for radiopharmaceutical preparations necessitate specific stipulations that must not only satisfy pharmaceutical drug quality, but also consider crucial radiation safety concerns to operators. Facility design and variation in certain chapter standards may be required and shall be documented with supporting evidence upon request.

(b) Radiopharmaceuticals prepared for oral administration shall be designated as, and conform to, the standards for non-sterile preparations. Any variation in certain chapter standards may be required to meet radiation safety concerns to operators and shall be documented with supporting evidence upon request.

### **PART 3. GOOD COMPOUNDING PRACTICES FOR STERILE PRODUCTS**

#### **535:15-10-50. Purpose**

(a) The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (non-sterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles or 10% for nonofficial articles, (4) unintended chemical and physical contaminants, and (5) ingredients of inappropriate quality in compounded sterile preparations (CSPs). Contaminated CSPs are potentially most hazardous to patients when administered into body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues. When CSPs contain excessive bacterial endotoxins they are potentially most hazardous to patients when administered into the central nervous system.

(b) To achieve the above five conditions and practices, this chapter provides minimum practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best sterile compounding practices. The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have

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been proven to be equivalent or superior with statistical significance to those described herein. The standards in this chapter do not pertain to the clinical administration of CSPs to patients via application, implantation, infusion, inhalation, injection, insertion, instillation, and irrigation, which are the routes of administration. Four specific categories of CSPs are described in this chapter: low-risk level, medium-risk level, and high-risk level, and immediate use. For the purposes of this chapter, CSPs include, but are not limited to the following:

(1) Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

(2) Manufactured sterile products prepared according to the instructions in manufacturers' approved labeling. Product package inserts usually refer to aseptic technique, but do not usually describe environmental quality controls, storage, or BUD and times for radiopharmaceuticals.

(c) All personnel who prepare CSPs shall be responsible for understanding these fundamental practices and precautions, for developing and implementing appropriate procedures, and for continually evaluating these procedures and the quality of final CSPs to prevent harm.

### **535:15-10-51. Definitions**

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

'ACPH' means 'air changes per hour'.

'ALARA' means 'as low as reasonably achievable'.

'Ante-Area' means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities are performed. It is also a transition area that (1) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas and (2) reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.

'Beyond-use date (BUD)' means the date and time, as appropriate, after which a compounded preparation is not to be used and is determined from the date the preparation is compounded.

'Biological Safety Cabinet (BSC)' means a ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

'Buffer Area' means an ISO Class 7 or better area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the staging of components and supplies used when compounding CSPs.

'Clean Room' means an ISO Class 5 or better room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

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'Component' means any ingredient used in the compounding of a drug product, including those that may not appear on the labeling of such a product.

'Compounder' is a pharmacist or anyone compounding under the direct supervision of a pharmacist pursuant to a prescription order by a licensed prescriber.

'Compounding' means the preparation, mixing, assembling, packaging, and labeling of a drug or device in accordance with a licensed practitioner's prescription drug order or under an initiative based on the Practitioner/Patient/Pharmacist relationship in the course of professional practice.

(A) Compounding may be for the purpose of, or as an incident to, research, teaching, or chemical analysis.

(B) Compounding includes the preparation of Drugs or Devices in anticipation of Prescription Drug Orders based on routine, regularly observed prescribing patterns.

(C) Reconstitution of commercial products is not considered compounding for the purposes of this subchapter.

(D) Manipulation of commercial available products according to or beyond the manufacturer's instructions or copying commercial products for the reason of non-availability or component specifications would be considered compounding as pertaining to a practitioner / patient / compounder relationship.

'Compounding Aseptic Containment Isolator (CACI)' means a compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) 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.

'Compounding Aseptic Isolator (CAI)' means a form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbially retentive filter (HEPA minimum).<sup>2</sup>

'Critical Site' means a location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.

'CSP' means 'Compounded Sterile Preparation'

'CSTD' means 'Closed-System Vial-Transfer Device'

'FDA' means the federal 'Food and Drug Administration'

'Hazardous drug' means any drug listed as such by NIOSH and/or any drug identified by at least one of the following six criteria: 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.

'HEPA' means 'High Efficiency Particulate Air'

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'Immediate Use' means 'administration begins not later than 1 hour following the start of the compounding procedure'.

'Inordinate Amount' means an amount of compounded drug that exceeds the amount a pharmacy anticipates may be used or dispensed before the BUD of the compounded drug and is unreasonable considering the intended use of the compounded drug.

'ISO' means 'International Organization for Standardization'

'ISO 5' means air containing no more than 100 P/ft<sup>3</sup> of air of a size at least 0.5 micron or larger in diameter (3520 P/m<sup>3</sup>), formerly FS209e Class 100.

'ISO 7' means air containing no more than 10,000 P/ft<sup>3</sup> of air of a size at least 0.5 micron or larger in diameter (352,000 P/m<sup>3</sup>), formerly FS209e Class 10,000.

'ISO 8' means air containing no more than 100,000 P/ft<sup>3</sup> of air of a size at least 0.5 micron or larger in diameter (3,520,000 P/m<sup>3</sup>), formerly FS209e Class 100,000.

'Isolator' means a device that is sealed or is supplied with air through a microbially retentive filtration system (HEPA minimum) and may be reproducibly decontaminated.

'Labeling' means a term that designates all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term 'label' designates that part of the labeling on the immediate container.

'LAFW' means 'Laminar Airflow Workbench'

'Manufacturing' means the production, 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 and includes any packaging or repackaging of the substance(s) or labeling or re-labeling of its container, for the promotion and marketing of such drugs or devices. Manufacturing also includes any preparation of a drug or device that is given or sold for resale by pharmacies, practitioners, or other persons. The distribution of inordinate amounts of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing.

'MDV' means 'Multiple Dose Vial'

'Media-Fill Test' means a test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. During this test, a microbiological growth medium such as Soybean-Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding.<sup>3</sup> The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

'Multiple-Dose Container' means a multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives.

'Negative Pressure Room' means a room that is at a lower pressure than the adjacent spaces and therefore, the net flow of air is into the room.

'NIOSH' means 'National Institute for Occupational Safety and Health'

'PEC' means 'Primary Engineering Control'

'PET' means 'Positron Emission Tomography'

'Personal Protective Equipment (PPE)' items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.

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**'Primary Engineering Control (PEC)'** means a device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

**'Preparation'** means an article compounded in a licensed pharmacy pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.

**'Product'** means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

**'Positive Pressure Room'** means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is out of the room.

**'Single-dose container'** means a single-dose, or a single-unit, container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

**'Segregated Compounding Area'** means a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.

**'Terminal Sterilization'** means the application of a lethal process (e.g., steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than  $10^{-6}$ , or a probability of less than one in one million of a non-sterile unit.

**'Unidirectional Flow'** means airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

**'USP'** means 'United States Pharmacopeia'

**535:15-10-52. Pharmacist responsibilities**

**(a) All Pharmacists who engage in drug compounding, shall be proficient in compounding and should continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature.**

**(b) Every pharmacist engaging in drug compounding must be familiar with all details of USP Compounding Standards.**

**(c) The pharmacist has the responsibility to:**

**(1) ensure the validity of all prescriptions**

**(2) certify all prescriptions.**

**(3) approve or reject all components, drug product containers, closures, in-process materials, and labeling.**

**(4) ensure preparations are of acceptable strength, quality, and purity.**

**(5) verify all critical processes to ensure that procedures will consistently result in the**

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expected qualities in the finished preparation.

(6) prepare and review all compounding records to ensure that no errors have occurred in the compounding process.

(7) ensure appropriate stability evaluation is performed or determined from the literature for establishing reliable beyond-use dating.

(8) ensure the proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice; and,

(9) ensure only authorized personnel shall be in the immediate vicinity of the drug compounding operation.

(10) perform final check of preparations prior to their release from the pharmacy.

(A) A check for compounding accuracy must ensure accuracy of the label and volumes or quantities of all drugs and solutions

(B) A visual examination procedure must ensure:

(i) Comparison with original order for initial dispensing

(ii) Accuracy of calculations

(iii) Use of proper solutions, additives and equipment

(iv) Labels are complete

(v) Proper assignment of beyond use date and time

(vi) Integrity of the container, including visual defects

(vii) Proper storage

(viii) Absence of particulate matter, precipitates, turbidity, discoloration, evidence of contamination or other signs that the preparation should not be used.

(C) The pharmacist shall reject and destroy all preparations that do not pass the final examination.

(D) Pharmacists shall document final preparation examinations prior to releasing the Compounded Sterile Preparations from the pharmacy.

(d) The pharmacist-in-charge has the responsibility to ensure that all compounders who compound sterile pharmaceuticals meet all requirements for training, testing and education set forth in these regulations and contained in the regulations set forth in USP standards.

(1) Competency shall be demonstrated prior to preparing any sterile products for patient use, and

(2) Whenever the quality assurance program yields unacceptable results, and

(3) Whenever unacceptable or questionable techniques are observed, and

(4) Evaluated at least annually.

(e) **Pharmacist requirements.** Any pharmacist in charge who performs or supervises the preparation or sterilization of sterile medications shall:

(1) Have available written policies and procedures for all steps in the compounding of sterile preparations. In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, aseptic technique, quality assurance, expiration dating, and other procedures as needed.

(2) Certify that all participating pharmacists and pharmacy technicians have completed training and testing program in sterile product preparation. Documentation of training and testing shall be available for review.

(3) Develop policies and procedures to annually test and review the techniques of

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participating pharmacists and pharmacy technicians to assure adherence to aseptic procedures.

(f) Staff will be trained and evaluated according as follows:

(1) Training is required for any individual who prepares sterile products. This training must be completed before the employee is allowed to prepare sterile products.

(2) Training may consist of any combination of didactic and experiential methods which must convey proper technique, infection control procedures, etc. required by USP standards.

(3) A written test shall be administered and passed based on the material referenced above upon initial hire or prior to assignment to prepare sterile products.

(4) Media-fill challenge tests will be used to evaluate sterile technique.

(5) Results of the media challenge tests shall be documented and logged.

(6) End product testing that results in a failure will result in a review of the aseptic technique of the individual involved.

(7) Testing involving media challenge tests will be conducted annually for every employee involved in sterile product preparation. Semiannual testing will be conducted for personnel involved in high-risk level compounding. Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately instructed and reevaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

(8) Glove fingertip sampling using processes compliant with the most current USP-required procedures shall be used to evaluate competency of personnel in performing hand hygiene and garbing procedures initially and at least annually.

(9) An 'Individual Training Record' shall be maintained for every employee involved in sterile product preparation.

(10) Nothing in these regulations shall prohibit a licensed student pharmacy intern engaged in experiential classes from assisting a properly qualified pharmacist in preparing sterile products under that pharmacist's direct supervision.

(11) Complete documentation by a pharmacist of training and testing shall be available for inspection.

(g) **Pharmacy technician requirements.** Pharmacy technicians participating in the preparation of sterile products shall have completed a pharmacist supervised training and testing program in sterile product preparation. Completed documentation by a pharmacist of training and testing shall be available for inspection.

**535:15-10-53. General requirements**

(a) Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product is generally prohibited unless patient therapy is compromised.

(b) However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is different from an FDA-approved drug that is commercially available based on documentation provided by the prescribing physician of a patient specific medical need (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available.

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(1) The unavailability of such drug product must be documented prior to compounding.

(2) This or similar documentation must be available when requested by the Board.

(c) Except for those products where stability prohibits advanced compounding, all products dispensed by the pharmacy shall be in a form ready for administration, except in health care facilities where medications may be provided as demanded by policies and procedures.

**535:15-10-54. CSP microbial contamination risk levels**

(a) **Sterile products.** Pharmacies and pharmacists dispensing sterile products shall comply with all applicable federal, state, and local law and regulation concerning pharmacy.

If the PEC (primary engineering control) is a compounding aseptic isolator that does not meet the environmental requirements described in USP <797> or is a laminar air-flow workbench (LAFW) or a biological safety cabinet (BSC) that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous CSPs pursuant to a physician's order for a specific patient may be prepared, and administration of such CSPs shall commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. Low-risk level CSPs with a 12-hour or less BUD shall meet all of the following criteria:

(1) PECs (LAFWs, BSCs, CAIs, CACIs,) shall be certified and maintain ISO Class 5 as described in USP <797> for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination.

(2) The segregated compounding area shall 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. Sinks should not be located adjacent to the ISO Class 5 PEC. Sinks should be separated from the immediate area of the ISO Class 5 PEC device.

(3) Personnel shall follow proper procedures for personnel cleansing and garbing prior to compounding and maintain proper competency of aseptic work practices.

(4) Personnel will follow proper procedures in ensure cleaning and disinfection of sterile compounding areas. Additionally, viable and non-viable environmental air sampling must be performed according to facility written procedures.

(b) **Risk level.** Requirements for preparation of sterile products will be based on the distinction of sterile products as either low-risk, medium-risk or high-risk products. These risk levels apply to the quality of CSPs immediately after the final aseptic mixing or filling or immediately after the final sterilization, unless precluded by the specific characteristics of the preparation.

(1) **Low-Risk Level CSPs.** Sterile products compounded under all of the following conditions are at a low risk of contamination:

(A) The CSPs are compounded with aseptic manipulations entirely within an ISO Class 5 environment or better air quality using only sterile ingredients, products, components, and devices.

(B) The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP.

(C) Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring

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sterile liquids in sterile syringes to sterile administration devices and package containers of other sterile products, and containers for storage and dispensing.

(2) **Medium-Risk Level CSPs.** When CSPs compounded aseptically under low-risk conditions, and one or more of the following conditions exists, such CSPs are at a medium risk of contamination.

(A) Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile product 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 the dissolution or homogeneous mixing.

(3) **High-risk sterile products.** CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated.

(A) Non-sterile ingredients are incorporated, or a non-sterile device is employed before terminal sterilization

(B) Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 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) Compounding personnel are improperly garbed and gloved as outlined by USP.

(D) Sterile water-containing preparations are stored for more than 6 hours before being sterilized.

(E) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or Compendial specifications in unopened or in opened packages of bulk ingredients.

(c) **Immediate use.** The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for Low-Risk Level subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are not intended for storage for anticipated needs or batch compounding. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs.

Immediate-use CSPs are exempt from the requirements described for *Low-Risk Level CSPs* only when all of the following criteria are met:

(1) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because

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they are hazardous drugs.

(2) Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.

(3) 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 non-sterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.

(A) Administration begins not later than 1 hour following the start of the preparation of the CSP. (B) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour beyond use date and time.

(C) If administration has not begun within 1 hour following the start of preparing the CSP; the CSP shall be promptly, properly, and safely discarded.

(d) Opened or needle-punctured single dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 air quality and any remaining contents must be discarded.

(e) Single-dose vials exposed to ISO Class 5 or cleaner air may be used for multiple needle entries up to 6 hours after initial needle puncture. Opened single-dose ampuls shall not be stored for any time period. Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives.

(f) The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days unless an alternate time period is otherwise specified by the manufacturer. This does not mean the expiration date of the unopened container.

(g) **Quality Assurance.** Quality assurance practices include, but are not limited to the following:

(1) Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality.

(2) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, such as eye protection and face masks.

(3) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.

(4) Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

(A) Semiannual certification of the primary engineering controls.

(B) Semiannual certification of nonviable environmental monitoring of all ISO 5, ISO 7, ISO 8 and segregated compounding areas.

(C) Semiannual certification of viable environmental monitoring of all ISO 5, ISO 7, ISO 8 and segregated compounding areas.

(D) Removable prefilters shall be inspected monthly, cleaned or changed at least quarterly or as directed by a qualified certifier, and the date documented.

(E) HEPA filters shall be repaired or replaced when recommended by a qualified certifier.

Initial and annual competence documentation of personnel, including

(i) Written test

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- (ii) Hand Hygiene and garbing
  - (iii) Gloved fingertip sampling
  - (iv) Aseptic manipulation
  - (v) Aseptic media-fill test
  - (vi) Cleaning and disinfecting
  - (vii) Surface sampling
  - (viii) Equipment
  - (ix) Routine visual inspection of all compounded sterile preparations
  - (x) Provision of guidelines to nursing education for competence documentation for non-pharmacy personnel who mix sterile preparations for immediate use
- (h) Quality control practices will include:
- (1) Daily documentation of temperature in areas where sterile products or sterile preparations are stored or compounded
  - (2) Daily documentation of the accuracy and precision of devices such as automated compounders and repeater pumps
- (i) The PIC or designee will prepare a periodic report of infection control procedures to track quality control and quality assurance activities, as appropriate.
- (j) Records of laminar air flow workbench maintenance and certification and ante-area, clean-room and buffer area certifications shall be kept in the pharmacy. A certification stamp shall be affixed to the hood.
- (k) **Storage.** All pharmacies preparing and dispensing compounded sterile products must provide:
- (1) Adequate controlled room temperature storage space for all raw materials.
  - (2) Adequate storage space for all equipment. All drugs and supplies shall be stocked on shelving above the floor.
  - (3) Adequate refrigerator storage space for compounded solutions, with routinely documented temperatures. Temperature ranges required are 36-46° F or 2-8° C.
  - (4) Adequate freezer storage space if finished products are to be frozen (e.g. reconstituted antibiotics.) There shall be a procedure to routinely document temperatures.
- (l) **Labeling.** In addition to regular labeling requirements, the label shall include:
- (1) Parenteral products shall have the rate of infusion when applicable.
  - (2) Expiration date (Policies and procedures shall address label change procedures as required by physician orders.)
  - (3) Storage requirements or special conditions.
  - (4) Name of ingredients and amounts contained in each dispensing unit.
  - (5) All products dispensed to outpatients, and removed from the site of preparation for administration different than the site of preparation, shall have label information as required by state law.
- (m) **Shipping.** Sterile product shipping:
- (1) Policies and procedures shall assure preparation storage requirements during delivery.
  - (2) Pharmacy must assure ability to deliver products within an appropriate time frame.
- (n) **Home patient care services.** The pharmacist in charge of the pharmacy dispensing sterile parenteral solutions shall provide the following or assure that they are provided prior to providing medications.
- (1) The pharmacist must assure that the patient is properly trained if self-administering.

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(2) In situations where a pharmacy or pharmacist employs a nurse to administer medications, the pharmacist in charge must:

(A) Employ a registered nurse.

(B) Assure that proper records are maintained in compliance with laws and regulations.

(C) Make these records available to inspectors from appropriate agencies.

(3) 24-hour service shall be assured by the pharmacy.

(4) Pharmacists shall recommend and monitor clinical laboratory data as requested.

(5) Side effects and potential drug interactions should be documented and reported to the physician.

(6) Patient histories and therapy plans should be maintained.

(o) **Pharmacist-in-charge responsibilities for high-risk sterile products.** When preparing high-risk sterile products, the pharmacist in charge is responsible for making sure the above procedures, in addition to the following, shall be met:

(1) Compound all medications in one of the following environments:

(A) A separate controlled limited access area with a positive air flow room inspected and certified as meeting ISO Class 7 requirements.

(B) An enclosed room providing an ISO Class 5 environment for compounding.

(C) A barrier isolator that provides an ISO Class 5 environment for compounding.

It is recommended that all pharmacies have an anteroom designed to be separate from the buffer room. The anteroom should be available for the decontamination of supplies and equipment, and donning of protective apparel. A sink should be available in the anteroom area so that personnel can scrub prior to entering the buffer room.

(2) Use total aseptic techniques, including gowning, mask, and hair net.

(3) Provide a system for tracking each compounded product including:

(A) Personnel involved in each stage of compounding;

(B) Raw materials used including quantities, manufacturer, lot number, and expiration date;

(C) Labeling;

(D) Compounding records shall be kept for 2 5 years.

(4) Establishment of procedures for sterilization of all products prepared with any non-sterile ingredients by filtration with 0.22 micron or other means appropriate for the product components.

(5) All high-risk level compounded sterile products for administration by injection into the vascular and central nervous systems that are prepared:

(A) in groups of more than twenty-five (25) identical individual single-dose packages (such as ampules, bags, syringes, and/or vials), or;

(B) in multiple dose vials for administration to multiple patients, or;

(C) are exposed longer than twelve (12) hours at a two (2) to eight (8) degrees centigrade and longer than six (6) hours at warmer than eight (8) degrees centigrade before they are sterilized; and shall be tested to ensure they are sterile, do not contain excessive bacterial endotoxins, and are of labeled potency before they are dispensed or administered as provided below.

(i) Sterility testing (bacterial and fungal) – The USP Membrane Filtration

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Method is the method of choice where feasible (e.g. components are compatible with the membrane). The USP Direct Transfer Method is preferred when the membrane filtration is not feasible. An alternative method may be used if verification results demonstrate that the alternative is at least as effective and reliable as the USP Membrane Filtration Method or the USP Direct Transfer Method. The pharmacist in charge shall establish written procedures requiring daily observation of the media and requiring an immediate recall if there is any evidence of microbial growth and said procedures must be available to Board inspectors.

(ii) Bacterial endotoxin (pyrogen) testing – The USP Bacterial Endotoxin Test, or verified equivalent, shall be used to ensure compounded sterile products do not contain excessive endotoxins.

(6) Establishment of procedures for yearly testing the techniques of pharmacists using simulated aseptic procedures and documentation thereof.

(7) Any facility improvements as required by this regulation (i.e. separate controlled limited access area and certification of ISO Class 5 must be complied with one year after approval of these rules.

**535:15-10-55. Drug compounding facilities**

(a) Pharmacies engaging in compounding shall have a specifically designated and adequate space for the orderly compounding of prescriptions, including the placement and storage of equipment and materials.

(b) The aseptic processing for sterile products shall be in an area separate and distinct from the area used for the compounding of non-sterile drug products. If parenteral products are being compounded, the rules in OAC 535:15-10-3.1 should be met. A primary engineering control (PEC), (laminar airflow workbench (LAFW), biological safety cabinet (BSC), compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI)) will be used to prepare all sterile preparations, except those compounded for Immediate Use.

(c) The area(s) used for the compounding of drugs shall be maintained in a good state of repair. These area(s) shall also be maintained in a clean and sanitary condition. Adequate washing facilities are to be provided and sewage, trash and other refuse in the compounding area is to be disposed of in a safe, sanitary, and timely manner.

(d) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored as directed by the manufacturer, or according to USP monograph requirements, in a clean, dry area under appropriate temperature conditions (controlled room temperature, refrigerator, or freezer in adequately labeled containers.) Bulk drugs shall also be stored such that they are protected from contamination.

(e) Adequate lighting and ventilation shall be provided in all compounding areas.

(f) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product.

(g) Work area and equipment. Any pharmacy dispensing compounded sterile preparations shall meet or exceed the following requirements:

(1) A separate controlled limited access area (also called a buffer area or buffer room) for compounding sterile solutions, which shall be of adequate space for compounding, labeling, dispensing, and sterile preparation of the medication. This area shall have

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controlled temperature. Cleanliness of the area is of critical importance. Drugs and other materials, taken into the limited access area, shall be removed from cardboard and other particle generating materials before being taken into the area.

(2) The controlled limited access area shall have a certified and inspected ISO Class 5 environment. Such an environment exists inside a certified laminar airflow hood (clean room, biological safety cabinet or other barrier isolator meeting ISO Class 5 requirements) used for the preparation of all compounded sterile products. The ISO Class 5 environment device or area is to be inspected and certified semiannually. Barrier isolator workstations are closed systems and are not as sensitive to their external environment as laminar airflow equipment. It is recommended to place them in a limited access area with cleaning and sanitizing in the surrounding area on a routine basis.

(3) A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the clean room and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column). In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.

(4) Hazardous drugs shall be prepared within a certified Class II, Type A (exhaust may be discharged to the outdoors) or Class II, Type B (exhaust may be discharged to the outdoors) laminar flow biological safety cabinet. Hazardous drug compounding shall have negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas, thus providing inward airflow to contain any airborne drug. All vented cabinets shall be vented through HEPA filtration, preferably to outside air or through use of suitable technology or equipment. Ventilation exhaust shall be placed as not to reenter the facility at any point.

(5) The area shall be designed to avoid excessive traffic and airflow disturbances.

(6) The area shall be ventilated in a manner not interfering with laminar flow hood conditions.

(7) Daily procedures must be established for cleaning the compounding area.

(8) PECs should be left on continuously. If a PEC has been turned off, allow the blowers to run continuously for at least 30 minutes before using.

**535:15-10-56. Compounding equipment**

(a) Equipment used in the compounding of drug products shall be of appropriate design and capacity as well as suitably located to facilitate operations for its intended use, cleaning and maintenance.

(b) Compounding equipment shall be of suitable composition so the surfaces that contact components shall neither be reactive, additive or absorptive, therefore not affecting or altering the purity of the product compounded preparation.

(c) Equipment and utensils used for compounding shall be thoroughly cleaned promptly after every use to prevent contamination and must be stored in a manner to protect from contamination.

(d) Defective equipment shall be clearly labeled as such.

(e) Automated, mechanical, electronic, limited commercial scale manufacturing or testing

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equipment, and other types of equipment may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated as necessary or checked to ensure proper performance.

(f) When drug products with special precautions (antibiotics and hazardous materials) are involved, appropriate measures must be utilized in order to prevent cross-contamination and proper disposal procedures must be followed. These measures include either the dedication of equipment for such operations or the meticulous cleaning of equipment prior to its use for the preparation of other drugs. Equipment dedicated for specific use (i.e. penicillin) shall be clearly designated as such.

#### **535:15-10-57. Component selection requirements**

(a) The pharmacists shall first attempt to use U.S.P.-NF drug substances and inactive component that have been made in an FDA registered facility.

(b) If components are not obtainable from a FDA registered facility or if the FDA and/or the company cannot document FDA registration, pharmacists compounding prescriptions shall use their professional judgment in first receiving, storing or using drug components that meet official compendia requirements or another high quality source.

(c) If components of compendial quality are non obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, American Chemical Society-certified, or Food Chemicals Codex grade may be used.

(d) Components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first.

#### **535:15-10-58. Control of drug product containers**

(a) Drug product containers and closures shall be handled and stored in a manner to prevent contamination and to permit inspection and cleaning of the work area.

(b) Containers and closures shall be of suitable material as to not alter the compounded drug as to quality, strength or purity of the compounded preparation.

#### **535:15-10-59. Drug compounding controls**

(a) There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality and purity they purport to have. These procedures should be available in either written form or electronically stored with printable documentation.

(b) The objective of the documentation is to allow another compounder to reproduce the identical prescription at a future date.

(c) Procedures shall include a listing of the components, their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. In addition, all equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug shall be listed.

(d) These written procedures shall be followed in the execution of the compounding procedure and are designed to enable a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation.

(e) Components shall be accurately weighed, measured, and subdivided as appropriate. These

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operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight and measure is correct as stated in the written compounding procedures.

(f) Written procedures shall be established and followed that describe the tests or examinations to be conducted on the product compounded (e.g., degree of variation) to ensure reasonable uniformity and integrity of compounded drug preparations. Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall contain not less than 90% and not more than 110% of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less than 90% and not more than 110% of the theoretically calculated weight or volume per unit of the preparation.

(1) Such control procedures shall be established to monitor the output and to verify the performance of those compounding processes that may be responsible for causing variability in the final drug product. These procedures shall include, but are not limited to, the following (where appropriate):

(A) Adequacy of mixing to assure uniformity and homogeneity;

(B) Clarity, completeness or pH of solutions.

(2) The compounder shall label any excess compounded products so as to reference them to the formula used, the assigned batch number, and beyond use date based on the compounder's appropriate testing, published data, or USP-NF standard.

(g) MSDS (material data safety sheet) files should be easily accessible.

**535:15-10-60. Transfer of sterile compounded prescriptions**

(a) If a patient requests a transfer of their prescription, a copy of the original prescription shall be transmitted upon the request of the receiving pharmacist.

(b) The information included in the transfer of the prescription shall include:

(1) Active ingredient(s)

(2) Concentration

(3) Dosage Form

(4) Route of delivery

(5) Delivery mechanism

(6) Dosing Duration i.e. Q12H, Q24H, Q72H

(7) Details about the compounding procedure must be reasonably available from the transferring pharmacy.

**535:15-10.61. Beyond use dating**

(a) Beyond-use dates (BUDs) shall be assigned to all compounded sterile preparations. The shorter of the chemical stability (established by the manufacturer, or listed in a current authoritative reference, or established by direct testing following USP standards or equivalent) and microbial limits of sterility (USP <797> requirements) shall be used to determine the date.

(1) If a pharmacy does not have a program of sterility and endotoxin testing in place and additional documentation for longer dates, then the following BUDs are to be used for compounded sterile preparations, (as illustrated in the Appendix A Chart):

(A) If USP <797> Risk Level is 'Immediate Use' Beyond Use Dates (BUD), and if kept

(i) at room temperature; use within 1 hour,

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(ii) refrigerated; use within 1 hour, or

(iii) in freezer, N/A.

(B) If USP <797> Risk Level is 'Low Risk' BUD, and if kept

(i) at room temperature, use within 48 hours,

(ii) refrigerated, use within 14 days, or

(iii) in freezer, use within 45 days.

(C) If USP <797> Risk Level is 'Low Risk with 12 hour or less' BUD, and if kept

(i) at room temperature use within 12 hours or less

(ii) refrigerated, use within 12 hours or less, or

(iii) in freezer, N/A

(D) If USP <797> Risk Level is 'Medium Risk' BUD, and if kept

(i) at room temperature, use within 30 hours,

(ii) refrigerated, use within 9 days, or,

(iii) in freezer, use within 45 days

(E) If USP <797> Risk Level is 'High Risk' BUD, and if kept

(i) at room temperature, use within 24 hours

(ii) refrigerated, use within 3 days, or

(iii) in freezer, use within 45 days

(2) If a pharmacy does have a program of sterility and endotoxin testing in place, then the BUDs for the non-sterile preparations are to be used, as previously presented in OAC 535:15-10-8.2.

(b) Reusable compounded preparations that are returned to a hospital pharmacy shall be placed in the refrigerator (unless contraindicated) with the original BUD on the label.

**535:15-10-62. Labeling**

(a) If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in, and stored in another container) the new container shall be identified with the:

(1) Component name,

(2) Lot and BUD if available,

(3) Strength and/or concentration, and;

(4) Weight or measure

(b) Products prepared in anticipation of a prescription prior to receiving a valid prescription should not be an inordinate amount.

(1) A regularly used amount should be prepared based on a history of prescriptions filled by the pharmacy.

(2) These products shall be labeled or documentation referenced with the:

(A) Complete list of ingredients or preparation name and reference,

(B) Preparation date,

(C) Assigned beyond-use date:

(i) Based on published data, or;

(ii) Appropriate testing, or;

(iii) U.S.P.-NF standards.

(D) Specific storage conditions dictated by composition and stability shall be specified (refrigerator, freezer, etc.), except where clean dry area is dictated, and;

(E) Batch or lot number.

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(c) Upon the completion of the drug preparation operation, the pharmacist shall examine the product for correct labeling.

(d) The outpatient prescription label shall contain the following:

- (1) Patient name,
- (2) Prescriber's name,
- (3) Name & address of pharmacy,
- (4) Directions for use,
- (5) Date filled,
- (6) Beyond use date & storage (may be auxiliary labels), and;
- (7) An appropriate designation that this is a compounded prescription, such as 'Compounded Rx'.

**535:15-10-63. Records and reports**

(a) Any procedures or other records required to comply with Good Compounding Practices shall be retained for the same period of time as required for retention of prescription records and copies of such records shall be readily available for authorized inspection.

(c) Computer information and the hard copy of the prescription should indicate that the prescription is to be compounded.

(d) Adequate records must be kept of controlled dangerous substances (Scheduled drugs) used in compounding.

**535:15-10-64. Compounding for institution and/or practitioner administration**

(a) The purpose of this section is to provide standards for the compounding of preparations pursuant to a prescription for a patient from a practitioner in a different health care facility or institutional pharmacy. Since compounding is already based on the practitioner/patient/pharmacist triad, this should be satisfied when a practitioner writes an order to administer the drug in the medical record.

(b) A compounded product shall NOT be sold to a third party for resale.

(c) A retail pharmacy that provides compounded preparations to an institutional pharmacy shall obtain a Compounding Drug Supplier Permit from the Board prior to such activity.

(d) A retail pharmacy that provides compounded preparations to practitioners for office use or to an institutional pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

- (1) Address acceptable standards of practice for each party entering into agreement and include a statement that the compounded preparation may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity
- (2) Include liability language, references to performance improvement and quality controls
- (3) require the practitioner or receiving pharmacy to include on patient's chart record, medication order, or medication administration record the lot batch number and BUD of the compounded preparation administered to a patient
- (4) Describe the scope of services to be performed by the filling pharmacy and practitioner or receiving pharmacy, including a statement of the process for:
  - (A) A patient to report an adverse reaction or submit a complaint; and
  - (B) The pharmacy to recall compounded preparations.

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(e) Records of orders and distributions of compounded preparations to a practitioner for office use or receiving pharmacy shall be kept by pharmacy for at least 5 years and be available for inspection. These records shall be maintained separately from the records of products dispensed pursuant to a prescription.

(f) Orders shall include the following information:

(1) Date of order

(2) Name, address and phone number of the practitioner who ordered the preparation and, if applicable, the name, address, and phone number of pharmacy to receive compounded preparation

(3) Name, strength, and quantity of preparation ordered.

(4) Patient name, when available.

(g) Distribution records shall include the following information:

(1) Date the preparation was compounded

(2) Date the preparation was distributed

(3) Name, strength, and quantity in each container of the preparation

(4) Lot number of the preparation

(5) Quantity of containers delivered

(6) Name, address, and phone number of the facility to whom the preparation is being distributed

(7) patient name, when available.

**535:15-10-65. Compounding of sterile hazardous drugs**

(a) Although the potential therapeutic benefits of compounded sterile and non-sterile hazardous drug preparations outweigh the risks of their adverse effects in ill patients, exposed healthcare workers risk similar adverse effects with no therapeutic benefit. Occupational exposure to hazardous drugs can result in:

(1) Acute effects, such as skin rashes;

(2) Chronic effects, including adverse reproductive events; and

(3) Possibly cancer.

Each facility must have a communication program that identifies hazardous drugs and communicates this list to all workers that participate in product acquisition, storage, transportation, housekeeping and waste disposal.

(b) Hazardous drugs shall be any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, or genotoxicity. A new or investigational drug that has no information on toxicity should be treated as a hazardous drug. At a minimum, the hazardous drug communication list shall be drugs received in the facility that are recognized as such by the National Institute for Occupational Safety and Health (NIOSH).

(c) Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas. Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure. Many hazardous drugs have sufficient vapor pressures that allow volatilization at room temperature; thus storage is preferably within a containment area such as a negative pressure room. The storage area should have sufficient general exhaust ventilation, at least 12 air changes per hour (ACPH) to dilute and remove any airborne contaminants.

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(d) Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal.

(e) Hazardous sterile drugs shall be prepared in an ISO Class 5 environment with protective engineering controls in place as specified in 535.15-10.5-5. Hazardous drug compounding shall have negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas, thus providing inward airflow to contain any airborne drug. All vented cabinets shall be vented through HEPA filtration, preferably to outside air or through use of suitable technology or equipment. Ventilation exhaust shall be placed as not to reenter the facility at any point.

(f) If a CACI that meets the requirements of this chapter is used outside of an ISO class 7 buffer area, the compounding area shall maintain negative pressure and have a minimum of 12 ACPHs. Manufacturer's guidelines or NISF guidelines shall be followed for isolators, containment hoods and BSC. Quality control certification for proper function shall be performed every six months by NISF certified personnel.

(g) When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment, Add-Vantage and PhaSeal) are used, they shall be used within the vented cabinet.

(h) In facilities that prepare a low volume, an average of no more than two per day, of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable.

(i) Appropriate personnel protective equipment (PPE) shall be worn when compounding hazardous drugs. PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, gloving with chemotherapy gloves; and compliance with manufacturers' recommendations when using a CACI.

(j) All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur prior to preparing or handling hazardous drugs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually. This training shall include didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it shall include ongoing training for each new hazardous drug that enters the marketplace. Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs. The training shall include at least the following: (1) safe aseptic manipulation practices; (2) negative pressure techniques when utilizing a BSC, powder containment hood or CACI; (3) correct use of CSTD devices; (4) containment, cleanup, and disposal procedures for breakages and spills; and (5) treatment of personnel contact and inhalation exposure.

(k) Consider a medical surveillance program or allow workers to have routine medical care.

(l) Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination.

**535:15-10-66. Compounding of sterile radiopharmaceuticals**

(a) In the case of production of radiopharmaceuticals for positron emission tomography (PET), the USP general test chapter *Radiopharmaceuticals for Positron Emission Tomography*—

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Compounding <823> supersedes this chapter or applicable federal manufacturing regulations. Upon release of a PET radiopharmaceutical as a finished drug product from a production facility, the further handling, manipulation, or use of the product will be considered compounding, and the content of this section and chapter is applicable.

(b) For the purposes of this chapter, radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container shall be designated as, and conform to, the standards for 'Low-Risk Level CSPs'

(c) The unique circumstances and requirements for radiopharmaceutical preparations necessitate specific stipulations that must not only satisfy pharmaceutical drug quality, but also consider crucial radiation safety concerns to operators. An integrated approach which addresses both aseptic and radiation safety techniques is necessary. Facility design and variation in certain chapter standards may be required and shall be documented with supporting evidence upon request.

(d) These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in an ISO Class 8 or cleaner air environment to permit compliance with applicable state and federal regulations.

(e) Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.

(f) Technetium-99m/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations. Such generator systems shall be eluted in an ISO Class 8 or cleaner air environment.

(g) Direct visual inspection of radiopharmaceutical CSPs shall be conducted in accordance with ALARA.

(h) The handling of radiopharmaceuticals is controlled through the licensing of 'Authorized Users' by the Oklahoma Department of Environmental Quality. As such, limited numbers of distribution channels exist to obtain radiopharmaceuticals. It is recognized that there is a special population that is outside the daily distribution range of a commercial nuclear pharmacy and that radiopharmaceuticals are not reasonably available. For these facilities, if the PEC is a CAI, CACI, a laminar airflow workbench (LAFW) or a biological safety cabinet (BSC) that cannot be located within an ISO Class 8 or better buffer area, then only low-risk CSPs pursuant to a physician's order may be prepared, and administration of such CSPs shall commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. These Low-risk level radiopharmaceutical CSPs with a 12-hour or less BUD shall be prepared in PECs (LAFWs, BSCs, CAIs, CACIs), which shall be certified and maintain ISO Class 5 and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination. A line of demarcation defining the segregated compounding area shall be established. Materials and garb exposed in a patient care and treatment areas must be cleaned before being brought into controlled compounding area. Other requirements as dictated by Low-Risk Radiopharmaceuticals shall be followed as described in this chapter.

(i) Preparation of radiopharmaceuticals for Immediate-Use category is reserved for radiopharmaceuticals needed for emergency or immediate patient care. Radiopharmaceuticals under this exemption shall apply only to diagnostic radiopharmaceuticals and administration must begin not later than one hour following the start of preparing the CSP. Certain

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preparations may necessitate more than two punctures into the same septum, i.e. Technetium 99mTc-Red Blood Cell labeling.

(j) Preparation of radio-labeled leukocytes or blood products requires the procedure be performed in an ISO Class 5 PEC that is located in an ISO Class 8 or cleaner air environment. Blood manipulations shall be clearly separated from routine procedures and have specific standard operating procedures to avoid cross contamination.

(k) Labeling requirements for this chapter do not supersede the labeling requirements of 535:15-17-5.

**535:15-10-67. Compounding of sterile allergen extracts**

(a) Allergen extracts as CSPs are single-dose and multiple-dose *intra*dermal or *sub*cutaneous injections that are prepared by specially trained physicians and pharmacy personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all *CSP Microbial Contamination Risk Levels* in this chapter only when all of the following criteria are met:

(1) The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection).

(2) All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Non-preserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.

(3) Before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either non-antimicrobial or antimicrobial soap and water.

(4) Compounding personnel don hair covers facial hair covers, gowns, and face masks.

(5) Compounding personnel perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity.

(6) Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations.

(7) Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen extracts as CSPs.

(8) Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs.

(9) The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other non-sterile materials) of critical sites (e.g., needles, opened ampuls, vial stoppers).

(10) The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications.

(11) Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.

(b) Personnel who compound allergen extracts as CSPs must be aware of greater potential risk

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of microbial and foreign material contamination when allergen extracts as CSPs are compounded in compliance with the foregoing criteria instead of the more rigorous standards in this chapter for CSP Microbial Contamination Risk Levels. Although contaminated allergen extracts as CSPs can pose health risks to patients when they are injected intradermally or subcutaneously, these risks are substantially greater if the extract is inadvertently injected intravenously.

Appendix A USP <797> Beyond-Use Date Limits Chart

<u>USP &lt;797&gt; Risk Level</u>	<u>Room Temperature</u>	<u>Refrigerated</u>	<u>Freezer</u>
<u>Immediate Use</u>	<u>1 hour</u>	<u>1 hour</u>	<u>N/A</u>
<u>Low Risk</u>	<u>48 hours</u>	<u>14 days</u>	<u>45 days</u>
<u>Low Risk with 12 hour or less BUD</u>	<u>12 hours or less</u>	<u>12 hours or less</u>	<u>N/A</u>
<u>Medium Risk</u>	<u>30 hours</u>	<u>9 days</u>	<u>45 days</u>
<u>High Risk</u>	<u>24 hours</u>	<u>3 days</u>	<u>45 days</u>

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## CHAPTER 20. MANUFACTURERS, PACKAGERS AND WHOLESALERS

### SUBCHAPTER 3. MANUFACTURERS

#### **535:20-3-1. Manufacturer permit [REVOKED]**

- ~~(a) A manufacturer permit entitles the permit holder to manufacture and wholesale Rx Only drugs (prescription drugs) from the licensed location.~~
- ~~(b) A manufacturer permit is only valid for the name, ownership and location listed on the permit.~~
- ~~(c) A new permit is required within 10 days if name, ownership or location changes.~~
- ~~(d) Each manufacturing location must be licensed.~~
- ~~(e) Each manufacturer whose product is sold in Oklahoma is required to obtain and maintain an Oklahoma manufacturer permit.~~

#### **535:20-3-1.1. Purpose**

- (a) The rules in this Subchapter set the minimum standards and requirement for persons who must license as a manufacturer as defined in 59 O.S. 353.1 before engaging in manufacturing as required in 59 O.S. Section 353.18 (B) and (C).
- (b) The rules of this Subchapter are to implement the requirement in the Pharmacy Practice Act and may include requirements for the Utilization of Used Prescription Medication Act.

#### **535:20-3-1.2. Definitions [RESERVED]**

#### **535:20-3-2. Registration; manufacturer permit requirement**

- (a) All manufacturers of Rx Only (dangerous) drugs conducting interstate and/or intrastate transactions in Oklahoma shall register annually with the Board of Pharmacy.
  - (1) Permits shall be issued only to those manufacturers which satisfy the provisions of Title 59, O.S., Section 353.18 (B)(1)(2) et seq., and all rules of this Title, et seq.
  - (2) Each manufacturer must comply with the Federal Food, Drug and Cosmetic Act Good Manufacturing Practices Act (GMPA, 21 U.S.C., Sec. 331 et seq.), the Prescription Drug Marketing Act of 1987 (PDMA, 21 U.S.C., Sec. 331 et seq.) and/or any other applicable federal, state, or local laws and regulations.
- (b) A manufacturer permit entitles the permit holder to manufacture and wholesale Rx Only drugs (prescription drugs) from the licensed location.
- (c) A manufacturer permit is only valid for the name, ownership and location listed on the permit.
- (d) A new permit is required within 10 days if name, ownership or location changes.
- (e) Each manufacturing location must be licensed.
- (f) Each manufacturer whose product is sold in Oklahoma is required to obtain and maintain an Oklahoma manufacturer permit.

#### **535:20-3-3. Minimum required information for permit**

- ~~The minimum required information for manufacturer licensure shall be as set forth in 535:20-7-4 regarding wholesalers and in 535:25 and this Title.~~
- (a) Applicants shall be registered with the federal Food and Drug Administration (FDA) as a manufacturer.
- (b) All manufacturer applicants must meet the requirements under the Oklahoma Pharmacy Act.

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this Title and the rules in 535:25 for applicants.

(c) Manufacturer applicants must submit a satisfactorily completed application together with the required fee annually. This application shall include, at least, the following:

- (1) The name, full business address, and telephone number;
- (2) All trade or business names used by the manufacturer applicant;
- (3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;
- (4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);
- (5) The name(s) of the owner and/or operator of the manufacturer applicant; and
- (6) Any other information the Board deems necessary to protect the public health.

**535:20-3-4. Minimum qualifications**

(a) All manufacturers must conform to the federal Good Manufacturing Practices GMPA, and/or any other applicable federal, state or local laws and regulations.

(b) The minimum qualifications for manufacturers shall be the same as those set forth in ~~535:20-7-5 regarding wholesalers~~ and in 535:25 and this Chapter.

(c) The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in manufacturer of drugs or devices:

- (1) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, manufacturer, wholesale or retail drug distribution, or distribution of controlled substances;
- (2) Any felony convictions of the applicant under federal, state, or local laws;
- (3) The applicant's past experience in the manufacture or distribution of drugs, including controlled substances;
- (4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug or device manufacturing or distribution;
- (5) Suspension, sanction, or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances; or by any of its owners for violation of state or federal laws regarding drugs or devices;
- (6) Compliance with licensing requirements under previously granted licenses, if any;
- (7) Compliance with requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section; and,
- (8) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(d) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

**535:20-3-5. Personnel**

—(a) Personnel employed in manufacturing shall have sufficient education, training and/or experience to perform assigned functions and comply with federal, state and local licensing requirements.

~~(b) The Board shall as required in 353.18(B), at a minimum, consider those qualifications listed in~~

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~~535:20-3-5 535:20-7-5 for personnel employed in wholesale distribution.~~

**535:20-3-6. Minimum requirements for Rx Only drug storage, handling, maintenance and records**

~~The minimum requirements for RX Only (dangerous) drug storage, handling, maintenance and records for manufacturers shall be the same as those set forth in 535:20-7-7 through 535:20-7-7.10 regarding wholesalers. The following decimal sections shall describe the minimum requirements for the storage and handing of drugs, and for the establishment and maintenance of drug records by manufacturers and their officers, agents, representatives, and employees.~~

**535:20-3-6.1. Facility requirements**

(a) All manufacturers of drugs shall conform to U. S. Food and Drug Administration (FDA) Current Good Manufacturing Practice Regulations (CGMP).

(b) All manufacturers shall conform to the Oklahoma Pharmacy Act and the rules of this Title.

(c) Each facility at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be licensed by the Board;

(2) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(3) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

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

(5) Be maintained in a clean and orderly condition; and,

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

**535:20-3-6.2. Multiple Licensing**

(a) A manufacturing facility shall not be in a facility where a retail pharmacy is located.

(b) The manufacturing facility shall be located apart and separate from any retail pharmacy, licensed by the Board of Pharmacy, as set forth in this Title and 535:25-3-5.

**535:20-3-6.3. Security**

(a) Each facilities used for manufacturing shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well-controlled.

(2) The outside perimeter of the premises shall be well-lighted.

(3) Entry into areas where drugs are held shall be limited to authorized personnel.

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

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

**535:20-3-6.4. Storage**

All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in

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the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

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

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs.

(3) The recordkeeping requirement in this Title for manufacturers shall be followed for all stored drugs.

**535:20-3-6.5. Examination of materials**

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or chemicals that are unfit. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

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

(c) The recordkeeping requirement in this Title for manufacturers shall be followed for all incoming and outgoing drugs.

**535:20-3-6.6. Returned, damaged, and outdated drugs**

(a) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed.

(b) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, quality, strength, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the manufacturer shall consider, among other things:

(1) The conditions under which the drug has been held, stored or shipped before or during its return; and,

(2) The condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(c) The recordkeeping requirements for manufacturers in this Title shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated drugs.

**535:20-3-6.7. Recordkeeping**

(a) Manufacturers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs.

(b) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the drugs.

(c) Records described in this section that are kept at the inspection site or that can be immediately

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retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.  
(d) Each manufacturer should maintain an ongoing list of persons with whom they do business.

**535:20-3-6.8. Written policies and procedures**

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

(b) Manufacturers shall include in their written policies and procedures the following:

(1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

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

(B) Voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(C) Action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

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

(3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.

(A) This procedure shall provide for written documentation of the disposition of outdated drugs.

(B) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

**535:20-3-6.9. Responsible persons**

Manufacturers shall establish and maintain lists of officers, directors, managers and other persons in charge of drug manufacturer, distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

**535:20-3-6.10. Compliance with federal, state and local laws**

(a) Manufacturers shall operate in compliance with applicable federal, state, and local laws and regulations.

(b) Manufacturers shall permit the Board of Pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.

(c) Manufacturers that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall

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comply with all applicable state, local and DEA regulations.

**535:20-3-6.11. Salvaging and reprocessing**

Manufacturers shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

**535:20-3-9. Prohibited conduct**

(a) The following shall be considered prohibited conduct and be a violation of these rules:

(1) Engaging in the manufacturing of drugs

(A) with intent to defraud or deceive, failing to maintain or provide a complete and accurate record, when required;

B) destroying, altering, concealing, or failing to maintain complete and accurate records for any drug manufactured, when required;

(C) knowingly purchasing or receiving drugs from a person, not authorized to distribute drugs, or,

(D) selling, bartering, brokering, or transferring drugs to a person not authorized to purchase drugs, under the jurisdiction in which the person receives the drug(s).

(2) Forging, counterfeiting, or falsely creating any label for a drug(s) or who falsely represents any factual matter contained in any label of a drug(s).

(3) Altering, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a drug or the commission of any other act with respect to a drug that results in the drug being misbranded.

(4) Manufacturing, purchasing, selling, delivering or bringing into the state contraband drug(s), or any one who illegally possesses any amount of contraband drug(s); or,

(b) Any violation of the rules of registrant conduct in 535:25-9 is prohibited conduct.

**SUBCHAPTER 5. PACKAGERS**

**535:20-5-1. Definitions**

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise;

**“Packager”** means packager as defined in Title 59 O.S. Section 353.1. ~~any~~ Any person, firm, or corporation, except a pharmacy, who transfers dangerous drugs from one container to another of any type.

**“Prescription drug”** means “prescription drug” as defined in Title 59 O.S. Section 353.1 ~~535:20-7-2 regarding wholesalers.~~

**“Wholesaler”** means a “Wholesaler” ~~“Wholesale distributor”~~ as defined in ~~535:20-7-2 regarding wholesalers~~ Title 59 O.S. Section 353.1.

**535:20-5-1.1. Purpose**

(a) The rules in this Subchapter set the minimum standards and requirement for persons who must license as a packager as defined in 59 O.S. 353.1 before engaging in packaging as required in 59 O.S. Section 353.18 (B) and (C).

(b) The rules of this Subchapter are to implement the requirement in the Pharmacy Practice Act.

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**535:20-5-2. Registration; packager permit requirements**

- (a) All packagers of Rx Only (dangerous) drugs conducting interstate and/or intrastate transactions in Oklahoma shall register annually with the Board of Pharmacy.
- (b) Permits shall be issued only to those packagers who possess a wholesaler permit and satisfy the provisions of:
- (1) Title 59, O.S., Section 353.18 (B)(1)(2) et seq.,
  - (2) the rules of this Title,
  - (3) the Federal Food, Drug and Cosmetic Act Good Manufacturing Practice Act (GMPA, 21 U.S.C., Sec. 331 et seq.);
  - (4) the Prescription Drug Marketing Act (PDMA, 21 U.S.C., Sec. 331 et seq.); and/or,
  - (5) any other applicable federal, state, or local laws and regulations.
- (c) A packager permit is only valid for the name, ownership and location listed on the permit.
- (d) A new packager permit is required within 10 days if name, ownership or location changes.
- (e) Each location shall possess a packager permit.
- (f) Each packager whose product is sold in Oklahoma is required to obtain and maintain an Oklahoma packager permit.

**535:20-5-3. Minimum required information for permit licensure**

~~The minimum required information for packager licensure shall be that information as required by the Oklahoma Pharmacy Act, the rules of this Chapter, 535:25, and the rules in 535:20-7-4 regarding wholesalers.~~

- (a) Applicants shall be registered with the federal Food and Drug Administration (FDA) and meet the federal requirements to repackage.
- (b) All packager applicants must meet the requirements under the Oklahoma Pharmacy Act, this Title and the rules in 535:25 for applicants.
- (c) Packager applicants must submit a satisfactorily completed application together with the required fee annually. This application shall include, at least, the following:
- (1) The name, full business address, and telephone number;
  - (2) All trade or business names used by the manufacturer applicant;
  - (3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;
  - (4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);
  - (5) The name(s) of the owner and/or operator of the manufacturer applicant; and
  - (6) Any other information the Board deems necessary to protect the public health.

**535:20-5-4. Minimum qualifications**

- (a) All packagers must conform to the federal Good Manufacturing Practices GMPA, and/or any other applicable federal, state or local laws and regulations.
- (b) The minimum qualifications for packagers shall be the same as those set forth in ~~535:20-7-5 regarding wholesalers the rules in 535:25 and this Chapter Title~~ for applicants and registrants.
- (c) The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in manufacturer of drugs or devices:
- (1) Any convictions of the applicant under any federal, state, or local laws relating to drug

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samples, manufacturer, wholesale or retail drug distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under federal, state, or local laws;

(3) The applicant's past experience in the manufacture or distribution of drugs, including controlled substances;

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

(5) Suspension, sanction, or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances; or by any of its owners for violation of state or federal laws regarding drugs or devices;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section; and,

(8) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(d) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

**535:20-5-5. Personnel**

—(a) Personnel employed in packaging shall have sufficient education, training and/or experience to perform assigned functions and comply with federal, state and local licensing requirements.

~~(b) The Board shall as required in 353.18(B), at a minimum, consider those qualifications listed in 535:20-7-5 for personnel employed in wholesale distribution.~~

**535:20-5-6. Minimum requirements for storage, handling, maintenance and records for RX Only drugs**

~~The minimum requirements for storage, handling, maintenance and records for Rx Only (dangerous) drugs for packagers shall be the same as those set forth in 535:20-7-7 through 535:20-7-7.10 regarding wholesalers. The following decimal sections shall describe the minimum requirements for the storage and handing of drugs, and for the establishment and maintenance of drug records by packagers and their officers, agents, representatives, and employees.~~

**535:20-5-6.1. Facility requirements**

(a) All packagers of drugs shall conform to U. S. Food and Drug Administration (FDA) Current Good Manufacturing Practice Regulations (CGMP).

(b) All packagers shall conform to the Oklahoma Pharmacy Act and the rules of this Title.

(c) Each facility at which drugs are packaged, stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be licensed by the Board;

(2) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(3) Have storage areas designed to provide adequate lighting, ventilation, temperature,

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sanitation, humidity, space, equipment and security conditions;

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

(5) Be maintained in a clean and orderly condition; and,

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

**535:20-5-6.2. Multiple Licensing**

(a) A packager facility shall not be in a facility where a retail pharmacy is located.

(b) The packager facility shall be located apart and separate from any retail pharmacy, licensed by the Board of Pharmacy, as set forth in this Title and 535:25-3-5.

**535:20-5-6.3. Security**

(a) Each facility used for packaging shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well-controlled.

(2) The outside perimeter of the premises shall be well-lighted.

(3) Entry into areas where drugs are held shall be limited to authorized personnel.

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

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

**535:20-5-6.4. Storage**

All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

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

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs.

(3) The recordkeeping requirement in this Title for manufacturers shall be followed for all stored drugs.

**535:20-5-6.5. Examination of materials**

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or chemicals that are unfit. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

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

(c) The recordkeeping requirement in this Title for manufacturers shall be followed for all incoming

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and outgoing drugs.

**535:20-5-6.6. Returned, damaged, and outdated drugs**

(a) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed.

(b) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, quality, strength, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the packager shall consider, among other things:

(1) The conditions under which the drug has been held, stored or shipped before or during its return; and,

(2) The condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(c) The recordkeeping requirements for packagers in this Chapter shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated drugs.

**535:20-5-6.7. Recordkeeping**

(a) Packagers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs.

(b) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the drugs.

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(d) Each packager should maintain an ongoing list of persons with whom they do business.

**535:20-5-6.8. Written policies and procedures**

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

(b) Packagers shall include in their written policies and procedures the following:

(1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

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

(B) Voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(C) Action undertaken to promote public health and safety by replacing of existing

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merchandise with an improved product or new package design.

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

(3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.

(A) This procedure shall provide for written documentation of the disposition of outdated drugs.

(B) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

**535:20-5-6.9. Responsible persons**

Packagers shall establish and maintain lists of officers, directors, managers and other persons in charge of drug manufacturer, distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

**535:20-5-6.10. Compliance with federal, state and local laws**

(a) Packagers shall operate in compliance with applicable federal, state, and local laws and regulations.

(b) Packagers shall permit the Board of Pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.

(c) Packagers that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulations.

**535:20-5-6.11. Salvaging and reprocessing**

Packagers shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

**535:20-5-9. Prohibited conduct**

(a) The following shall be considered prohibited conduct and be a violation of these rules:

(1) Engaging in the packaging and/or distribution of drugs

(A) with intent to defraud or deceive, failing to maintain or provide a complete and accurate record, when required;

(B) destroying, altering, concealing, or failing to maintain complete and accurate records for any drug packaging, when required;

(C) knowingly purchasing or receiving drugs from a person, not authorized to distribute drugs, or,

(D) selling, bartering, brokering, or transferring drugs to a person not authorized to purchase drugs, under the jurisdiction in which the person receives the drug(s).

(2) Forging, counterfeiting, or falsely creating any label for a drug(s) or who falsely represents any factual matter contained in any label of a drug(s).

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(3) Altering, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a drug or the commission of any other act with respect to a drug which results in the drug being misbranded.

(4) Packaging, purchasing, selling, delivering or bringing into the state contraband drug(s), or any one who illegally possesses any amount of contraband drug(s); or,

(b) Any violation of the rules of registrant conduct in 535:25-9 is prohibited conduct.

## **SUBCHAPTER 7. WHOLESALERS AND PEDIGREE RULES**

### **535:20-7-7.7. Recordkeeping; including pedigree requirement**

(a) Wholesale distributors shall establish and maintain complete inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs and devices.

(b) After January 1, ~~2009~~2011, each person who is engaged in wholesale distribution of prescription drugs, (including repackagers of the finished form of the prescription drug) whether located in or out-of-state, must maintain and provide a pedigree record developed in accordance with standards and requirements of the Board, for all drugs received, distributed, sold and/or offered for sale outside of the normal distribution channel, or that leave or have ever left the normal distribution channel and shall before each wholesale distribution of such drug provide a pedigree to the person who receives such prescription drug.

(1) A statement or record in written or electronic form shall be used to record each distribution of any given drug, from the sale by a manufacturer through acquisition and sale by any wholesaler distributor, packager and/or repackager.

(2) The pedigree shall include, but not be limited to, the following information for each transaction:

(A) The source of the drug(s), including the name and principal address of the seller;

(B) The name of the drug and the national drug code (NDC) number, the amount of the drug, the date of the purchase, quantity (container size, number of containers), and lot number(s) of the drug;

(C) The business name and address of each owner of the drug, its shipping information, including the name and address of the facility of each person certifying delivery or receipt of the drug;

(D) A certification that the information contained therein is true and accurate under penalty of perjury.

(3) The wholesale distributor must conduct due diligence in verifying pedigrees.

(4) The pedigree or electronic record requirements do not apply to compressed medical gases (medical gas suppliers and medical gas distributors, etc.)

(5) The pedigree or electronic record requirements do not apply to drugs labeled for veterinarian use.

(c) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution, or other disposition of all drugs and devices. Such records shall include the dates of receipt and distribution or other disposition of the drugs and devices. Inventories and records shall be maintained and made available for inspection and photocopying for a period of two (2) years following their creation date.

(1) Records described in this section that are kept at the inspection site or that can be

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immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.

(2) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a

federal, state, or local law enforcement agency.

(d) Each wholesale distributor should maintain an ongoing list of persons with whom they do business.

## SUBCHAPTER 9. MEDICAL GAS SUPPLIERS AND DISTRIBUTORS

### 535:20-9-3. Medical gas suppliers

(a) **Licensing requirement.** Before conducting interstate and/or intrastate transactions in Oklahoma, a medical gas supplier shall register annually with ~~must be licensed by~~ the Board of Pharmacy.

(1) A medical gas supplier permit is only valid for the name, ownership and location listed on the permit. Changes of name, ownership or location shall require a new medical gas supplier permit.

(2) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. manager, contact person, phone, etc.)

(3) Each location shall possess a medical gas supplier permit. A medical gas supplier permit entitles the permit holder to store and supply medical gas (prescription drugs) at the licensed location.

(b) Permits shall be issued only to those medical gas suppliers who satisfy the provisions of:

(1) Title 59, O.S., Section 353.18 (B)(1)(2) et seq.,

(2) All medical gas supplier applicants must meet the requirements under the Oklahoma Pharmacy Act, this Title and the rules in 535:25 for applicants.

(3) Applicants shall be registered with the federal Food and Drug Administration (FDA) and meet the federal requirements to handle medical gas.

(4) The Prescription Drug Marketing Act (PDMA, 21 U.S.C., Sec. 331 et seq.); and/or,

(5) Any other applicable federal, state, or local laws and regulations.

(c) ~~(b)~~ **Minimum required information for licensure.** The minimum required information for medical gas supplier licensure shall be as follows, ~~same as that information required by 535:20-7-4 regarding wholesalers.~~ Medical gas supplier applicants must submit a satisfactorily completed application together with the required fee annually. This application shall include, at least, the following:

(1) The name, full business address, and telephone number;

(2) All trade or business names used by the manufacturer applicant;

(3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;

(4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);

(5) The name(s) of the owner and/or operator of the manufacturer applicant; and

(6) Any other information the Board deems necessary to protect the public health.

(d) ~~(c)~~ **Minimum qualifications.** Medical gas suppliers must conform to the Compressed

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Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(1) Medical gas suppliers must conform to all applicable federal, state or local laws and regulations.

(2) The minimum qualifications shall be the same as those set forth in 535:25-535:20-7-5 regarding wholesalers, and this Chapter. The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in the supplying of medical gases:

(A) Any convictions of the applicant under any federal, state, or local laws relating to drugs, drug samples, manufacture, packager, wholesale or retail drug distribution, or distribution of controlled substances;

(B) Any felony convictions of the applicant under federal, state, or local laws;

(C) The applicant's past experience in the handling, manufacture, packaging or distribution of drugs, including controlled substances;

(D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug or device handling, manufacturing, packing, or distribution;

(E) Suspension, sanction, or revocation by federal, state, or local government of any license currently or previously held by the applicant for the handling, manufacture, packaging, or distribution of any drugs, including controlled substances; or by any of its owners for violation of state or federal laws regarding drugs or devices;

(F) Compliance with licensing requirements under previously granted licenses, if any;

(G) Compliance with requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section; and,

(H) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(3) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

~~(e)-(d)~~ **Personnel.** Personnel employed by medical gas suppliers shall have sufficient education, training, and/or experience to perform assigned functions and comply with federal, state and local licensing requirements. ~~The Board shall as required in 353.18(B), at a minimum, shall consider those qualifications listed in 535:20-7-5 and 535:20-7-6 for personnel employed in wholesale distribution.~~

~~(f)~~ ~~(e)~~ **Minimum requirements for storage, handling, and records.** Medical gas suppliers must meet minimum requirements for storage and handling, and for the establishment and maintenance of distribution records for medical gases.

(1) The following shall describe the minimum requirements for the storage and handing of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas suppliers and their officers, agents, representatives, and employees.

(A) All medical gas suppliers of drugs shall conform to U. S. Food and Drug Administration (FDA) requirements for medical gas prescription drugs.

(B) All medical gas suppliers shall conform to the Oklahoma Pharmacy Act and the rules of this Title.

(C) Each facility at which drugs are stored, warehoused, handled, held, offered,

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marketed, or displayed shall:

(i) Be licensed by the Board;

(ii) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(iii) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

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

(v) Be maintained in a clean and orderly condition; and

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

(2) Medical gases housed by a medical gas supplier shall conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(g) (f) **Prescription requirement Requirements.** Medical gas suppliers shall not supply medical gas without a drug order. Drug orders may be issued for institutional or licensed medical practitioner office use as well as to a patient.

(1) An original or copy of a prescription drug order must be kept at the licensed location supplying the medical gas.

(2) A prescription drug order is only valid for one (1) year. Prescription drug orders shall be maintained for five years and be readily retrievable and available at inspection.

(h) **Minimum requirements for storage, handling, and records for medical gas.** The following shall describe the minimum requirements for the storage and handing of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas suppliers and their officers, agents, representatives, and employees.

(1) **Security.** Each facility used for medical gases shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well-controlled.

(B) The outside perimeter of the premises shall be well-lighted.

(C) Entry into areas where drugs are held shall be limited to authorized personnel.

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

(2) **Storage.** All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

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

(B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs, if required.

(C) The recordkeeping requirement in this Chapter for medical gas suppliers shall be

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followed for all stored drugs.

**(3) Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or chemicals that are unfit. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

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

(B) The recordkeeping requirement in this Chapter shall be followed for all incoming and outgoing drugs.

**(4) Returned, damaged, and outdated drugs.** Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed.

(A) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, quality, strength, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the medical gas supplier shall consider, among other things:

(i) The conditions under which the drug has been held, stored or shipped before or during its return; and,

(ii) The condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(B) The recordkeeping requirements for medical gas suppliers in this Chapter shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated drugs.

**(5) Recordkeeping.** Medical gas suppliers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs.

(A) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the drugs.

(B) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(C) Each medical gas supplier should maintain an ongoing list of persons with whom they do business.

**(6) Written policies and procedures.** Medical gas suppliers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(A) Medical gas suppliers shall include in their written policies and procedures the

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following:

(i) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

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

(II) Voluntary action by the medical gas supplier to remove defective or potentially defective drugs from the market; or

(III) Action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(B) A procedure to ensure that medical gas suppliers prepare for, protect against, and handle a crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency.

(C) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.

(i) This procedure shall provide for written documentation of the disposition of outdated drugs.

(ii) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

(7) **Responsible persons.** Medical gas suppliers shall establish and maintain lists of officers, directors, managers and other persons in charge of drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(8) **Compliance with federal, state and local laws.** Medical gas suppliers shall operate in compliance with applicable federal, state, and local laws and regulations.

(A) Medical gas suppliers shall permit the Board of Pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.

(B) Medical gas suppliers that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulation.

(9) **Salvaging and reprocessing.** Medical gas suppliers shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

**535:20-9-4. Medical gas distributors**

(a) **Licensing requirement.** Before conducting interstate and or intrastate transactions in Oklahoma, a medical gas distributor shall register annually with ~~must be licensed by~~ the Board of Pharmacy.

(1) A medical gas distributor permit is only valid for the name, ownership and location listed on the permit. Changes of name, ownership or location shall require a new medical gas distributor permit.

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(2) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. manager, contact person, phone, etc.)

(3) Each location shall possess a medical gas distributor permit. Medical gas distributor permit entitles the permit holder to store and distribute medical gas (prescription drugs) at the licensed location.

(b) Permits shall be issued only to those medical gas distributors who satisfy the provisions of:

(1) Title 59, O.S., Section 353.18 (B)(1)(2) et seq.,

(2) All medical gas distributor applicants must meet the requirements under the Oklahoma Pharmacy Act, this Title and the rules in 535:25 for applicants.

(3) Applicants shall be registered with the federal Food and Drug Administration (FDA) and meet the federal requirements to handle and wholesale medical gas.

(4) The Prescription Drug Marketing Act (PDMA, 21 U.S.C., Sec. 331 et seq.); and/or,

(5) Any other applicable federal, state, or local laws and regulations.

(c) ~~(b)~~ **Minimum required information for licensure.** The minimum required information for medical gas distributors licensure shall be the same as follows, that information required by 535:20-7-4 regarding wholesalers. Medical gas distributor applicants must submit a satisfactorily completed application together with the required fee annually. This application shall include, at least, the following:

(1) The name, full business address, and telephone number;

(2) All trade or business names used by the manufacturer applicant;

(3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;

(4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);

(5) The name(s) of the owner and/or operator of the manufacturer applicant; and

(6) Any other information the Board deems necessary to protect the public health.

(d) ~~(c)~~ **Minimum qualifications.** Medical gas distributors must conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(1) Medical gas distributors must conform to all applicable federal, state or local laws and regulations.

(2) The minimum qualifications shall be the same as those set forth in ~~535:20-7-5 regarding wholesalers.~~ 535:25 and this Chapter. The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in medical gas distribution:

(A) Any convictions of the applicant under any federal, state, or local laws relating to drugs, drug samples, manufacture, packager, wholesale or retail drug distribution, or distribution of controlled substances;

(B) Any felony convictions of the applicant under federal, state, or local laws;

(C) The applicant's past experience in the handling, manufacture, packaging or distribution of drugs, including controlled substances;

(D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug or device handling, manufacturing, packing, or distribution;

(E) Suspension, sanction, or revocation by federal, state, or local government of any

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license currently or previously held by the applicant for the handling, manufacture, packaging, or distribution of any drugs, including controlled substances; or by any of its owners for violation of state or federal laws regarding drugs or devices;

(F) Compliance with licensing requirements under previously granted licenses, if any;

(G) Compliance with requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section; and,

(H) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(3) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

~~(e) (d)~~ **Personnel.** Personnel employed by medical gas distributors shall have sufficient education, training, and/or experience to perform assigned functions and comply with federal, state and local licensing requirements. ~~The Board shall as required in 353.18(B), at a minimum, consider those qualifications listed in 535:20-7-5 and 535:20-7-6 for personnel employed in wholesale distribution.~~

~~(f) (e)~~ **Minimum requirements.** Medical gas distributors must meet minimum requirements for storage and handling, and for the establishment and maintenance of distribution records for medical gases.

~~(1) These minimum requirements shall be the same as those set forth in 535:20-7-7.3 regarding wholesalers security, except for Paragraphs (2) and (3) of Subsection (a) and 535:20-7-7.4 regarding storage except for Paragraphs (1) and (2) of Subsection (a). The following shall describe the minimum requirements for the storage and handing of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas distributors and their officers, agents, representatives, and employees.~~

~~(A) All medical gas distributors of drugs shall conform to U. S. Food and Drug Administration (FDA) requirements for medical gas prescription drugs.~~

~~(B) All medical gas distributors shall conform to the Oklahoma Pharmacy Act and the rules of this Title.~~

~~(C) Each facility at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:~~

~~(i) Be licensed by the Board;~~

~~(ii) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;~~

~~(iii) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;~~

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

~~(v) Be maintained in a clean and orderly condition; and,~~

~~(vi) Be free from infestation by insects, rodents, birds, or vermin of any kind.~~

(2) Medical gases housed by a medical gas distributor shall conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

~~(g) (f)~~ **Prescription requirements Requirements.** Medical gas distributors shall distribute only

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to an entity licensed to receive medical gas or upon a practitioner's drug order. A pharmacy, dentist, or licensed practitioner's practice license verifies their authority to receive Rx Only medical gases.

- (1) An original or copy of a prescription drug order must be kept at the licensed location distributing the medical gas.
- (2) A prescription drug order is only valid for one (1) year. Prescription drug orders shall be maintained for five years and be readily retrievable and available at inspection.
- (3) Distributors that sell to licensed medical gas suppliers must keep an updated copy of each supplier's license on file.

**(h) Minimum requirements for storage, handling and records for medical gas Rx Only drugs.** The following shall describe the minimum requirements for the storage and handing of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas distributors and their officers, agents, representatives, and employees.

- (1) **Security.** Each facility used for medical gases shall be secure from unauthorized entry.
  - (A) Access from outside the premises shall be kept to a minimum and be well-controlled.
  - (B) The outside perimeter of the premises shall be well-lighted.
  - (C) Entry into areas where drugs are held shall be limited to authorized personnel.
  - (D) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (2) **Storage.** All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).
  - (A) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
  - (B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs, if required.
  - (C) The recordkeeping requirement in this Chapter for medical gas distributors shall be followed for all stored drugs.
- (3) **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or chemicals that are unfit. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
  - (A) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.
  - (B) The recordkeeping requirement in this Chapter shall be followed for all incoming and outgoing drugs.
- (4) **Returned, damaged, and outdated drugs.** Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from

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other drugs until they are destroyed.

(A) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, quality, strength, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the medical gas distributors shall consider, among other things:

(i) The conditions under which the drug has been held, stored or shipped before or during its return; and,

(ii) The condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(B) The recordkeeping requirements for medical gas distributors in this Chapter shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated drugs.

**(5) Recordkeeping.** Medical gas distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs.

(A) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the drugs.

(B) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(C) Each medical gas distributor should maintain an ongoing list of persons with whom they do business.

**(6) Written policies and procedures.** Medical gas distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(A) Medical gas distributors shall include in their written policies and procedures the following:

(i) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

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

(II) Voluntary action by the medical gas distributor to remove defective or potentially defective drugs from the market; or

(III) Action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(B) A procedure to ensure that medical gas distributors prepare for, protect against, and

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handle a crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency.

(C) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.

(i) This procedure shall provide for written documentation of the disposition of outdated drugs.

(ii) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

(7) **Responsible persons.** Medical gas distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(8) **Compliance with federal, state and local laws.** Medical gas distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(A) Medical gas distributors shall permit the Board of Pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.

(B) Medical gas distributors that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulation.

(9) **Salvaging and reprocessing.** Medical gas distributors shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

**535:20-9-6. Prohibited conduct**

(a) The following shall be considered prohibited conduct and be a violation of these rules:

(1) Engaging in medical gas distributing of drugs

(A) with intent to defraud or deceive, failing to maintain or provide a complete and accurate record, when required;

(B) destroying, altering, concealing, or failing to maintain complete and accurate records for any drug packaging, when required;

(C) knowingly purchasing or receiving drugs from a person, not authorized to distribute drugs, or,

(D) selling, bartering, brokering, or transferring drugs to a person not authorized to purchase drugs, under the jurisdiction in which the person receives the drug(s).

(2) Forging, counterfeiting, or falsely creating any label for a drug(s) or who falsely represents any factual matter contained in any label of a drug(s).

(3) Altering, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a drug or the commission of any other act with respect to a drug that results in the drug being misbranded.

(4) supplying, packaging, purchasing, selling, delivering or bringing into the state contraband drug(s), or any one who illegally possesses any amount of contraband drug(s); or,

(b) Any violation of the rules of registrant conduct in 535:25-9 is prohibited conduct.

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## CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS

### SUBCHAPTER 3. APPLICANTS, REGISTRANTS AND APPLICATIONS

#### **535:25-3-4. Requirements for applicants or registrants who have had action against any license, permit or certificate**

(a) If the Board approves an applicant or registrant who has had a previous registration, license, permit, or certificate which was revoked or subject to Board action at cancellation, the applicant shall be subject to the following terms:

(1) A minimum of two years probation.

(2) Any specific requirements placed on the applicant by the Board based on the previous action and applicant's or registrant's current status.

(3) Any violations by the applicant or registrant shall subject the applicant or registrant to cumulative action based on previous violation on the previous license and the current violation.

(4) Failure of the applicant or registrant to meet any terms or requirements of the Board shall subject the applicant to Board action based on current failure and previous Board action against previous License

(e) (b) The Board shall have the right to order any additional terms or conditions that it determines are required to protect the public health and safety.

### SUBCHAPTER 9. VIOLATIONS OF THE RULES OF REGISTRANT CONDUCT

#### **535:25-9-8. Failure to maintain effective controls**

(a) Failure Failing to establish and maintain effective controls to prevent prescription errors is a violation of registrant conduct.

(b) Failure to establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules is a violation of registrant conduct.

(c) The sale of dangerous drugs to a person or entity not eligible to receive such drugs is a violation of registrant conduct.

(d) The purchase of dangerous drugs from a person or entity not eligible to possess such drugs is a violation of registrant conduct.