

AGENDA

March 25, 2009

OKLAHOMA STATE BOARD OF PHARMACY
4545 Lincoln Boulevard, Suite 112
Oklahoma City, Oklahoma 73105-3488

PROPOSED PERMANENT RULE HEARING

TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY

1:00 p.m. Call meeting to order.

CHAPTER 1. ADMINISTRATIVE OPERATIONS

PROPOSED RULES:

- SUBCHAPTER 5 GENERAL COURSE IN METHOD OF OPERATIONS
 - 535:1-5-5.1 Complaint confidentiality

- SUBCHAPTER 7 INDIVIDUAL PROCEEDINGS
 - 535:1-7-2 Serving of notices
 - 535:1-7-4 Failure to appear or failure to comply
 - 535:1-7-5 Subpoenas
 - 535:1-7-7 Final orders

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

PROPOSED RULES:

- SUBCHAPTER 3 PHARMACISTS
 - 535:10-3-4 Uniform pharmacy continuing education

- SUBCHAPTER 5 INTERNS, PRECEPTORS AND TRAINING AREAS
 - 535:10-5-1.1 Purpose
 - 535:10-5-1.2 Definitions
 - 535:10-5-3 Intern requirements; licenses
 - 535:10-5-4 Intern practice requirements
 - 535:10-5-5 Intern credit hours; computation
 - 535:10-5-9 Training area requirements
 - 535:10-5-13 Intern file destruction

- SUBCHAPTER 7 PHARMACIST LICENSURE
 - 535:10-7-8 Foreign pharmacy graduates licensure applicants

- SUBCHAPTER 11 PHARMACIST ADMINISTRATION OF IMMUNIZATIONS
 - 535:10-11-3 D.Ph. administering of immunization requirements
 - 535:10-11-5 D.Ph. training requirements for administration of immunizations

CHAPTER 15. PHARMACIES

PROPOSED RULES:

- SUBCHAPTER 3 PHARMACIES
 - 535:15-3-4.1 Pharmacy licensing requirement
 - 535:15-3-9 Non-resident pharmacies
 - 535:15-3-10 Inventory
 - 535:15-3-13 Pharmacist's responsibility in a pharmacy

- SUBCHAPTER 6 HOSPITAL DRUG ROOMS
 - 535:15-6-4 Staffing requirements
 - 535:15-6-11 Administration of drugs to patients

CHAPTER 20. MANUFACTURERS, PACKAGERS AND WHOLESALERS

PROPOSED RULES:

- SUBCHAPTER 3 MANUFACTURERS
 - 535:20-3-1 Manufacturer permit [REVOKED]
 - 535:20-3-1.1 Purpose [NEW]
 - 535:20-3-1.2 Definitions [RESERVED]
 - 535:20-3-2 Registration; manufacturer licensing, registration or permit requirement [AMENDED]
 - 535:20-3-3. Minimum required information for licensure [AMENDED]

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- 535:20-3-4 Minimum qualifications [AMENDED]
- 535:20-3-5 Personnel [AMENDED]
- 535:20-3-6 Minimum requirements for Rx Only drug storage, handling, maintenance and records [AMENDED]
- 535:20-3-6.1 Facility requirements [NEW]
- 535:20-3-6.2 Multiple Licensing [NEW]
- 535:20-3-6.3 Security [NEW]
- 535:20-3-6.4 Storage [NEW]
- 535:20-3-6.5 Examination of materials [NEW]
- 535:20-3-6.6 Returned, damaged, and outdated drugs [NEW]
- 535:20-3-6.7 Recordkeeping [NEW]
- 535:20-3-6.8 Written policies and procedures [NEW]
- 535:20-3-6.9 Responsible persons [NEW]
- 535:20-3-6.10 Compliance with federal, state and local laws [NEW]
- 535:20-3-6.11 Salvaging and reprocessing [NEW]
- 535:20-3-9 Prohibited conduct [NEW]

SUBCHAPTER 5 PACKAGERS

- 535:20-5-1 Definitions [AMENDED]
- 535:20-5-1.1 Purpose
- 535:20-5-2 Registration; packager permit requirements
- 535:20-5-3 Minimum required information for licensure
- 535:20-5-4 Minimum qualifications
- 535:20-5-5 Personnel
- 535:20-5-6 Minimum requirements for storage, handling, maintenance and records
- 535:20-5-6.1 Facility requirements
- 535:20-5-6.2 Multiple Licensing
- 535:20-5-6.3 Security
- 535:20-5-6.4 Storage
- 535:20-5-6.5 Examination of materials
- 535:20-5-6.6 Returned, damaged, and outdated drugs
- 535:20-5-6.7 Recordkeeping
- 535:20-5-6.8 Written policies and procedures
- 535:20-5-6.9 Responsible persons
- 535:20-5-6.10 Compliance with federal, state and local laws
- 535:20-5-6.11 Salvaging and reprocessing
- 535:20-5-9 Prohibited conduct

SUBCHAPTER 7 WHOLESALERS AND PEDIGREE RULES

- 535:20-7-7.7 Recordkeeping; including pedigree requirement

SUBCHAPTER 9 MEDICAL GAS SUPPLIERS AND DISTRIBUTORS

- 535:20-9-3 Medical gas suppliers
- 535:20-9-4 Medical gas distributors
- 535:20-9-6 Prohibited conduct

CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS

PROPOSED RULES:

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

SUBCHAPTER 9 VIOLATIONS OF THE RULES OF REGISTRANT CONDUCT

- 535:25-9-8 Failure to maintain effective controls

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CHAPTER 15. PHARMACIES

PROPOSED RULES:

SUBCHAPTER 10 GOOD COMPOUNDING PRACTICES

PART 1. GOOD COMPOUNDING PRACTICES FOR NON-STERILE PRODUCTS

- 535:15-10-1 Purpose
- 535:15-10-2 Definitions
- 535:15-10-3 Pharmacist responsibilities
- 535:15-10-4 Drug compounding facilities
- 535:15-10-5 Compounding equipment
- 535:15-10-6 Component selection requirements
- 535:15-10-7 Control of drug product containers
- 535:15-10-8 Drug compounding controls
- 535:15-10-8.1 Transfer of compounded prescription
- 535:15-10-8.2 Beyond-use dating
- 535:15-10-9 Labeling
- 535:15-10-10 Records and reports
- 535:15-10-11 Pharmacy generated product requirements
- 535:15-10-12 Compounding for a prescriber's office use
- 535:15-10-13 Compounding veterinarian products
- 535:15-10-14 Compounding of non-sterile hazardous drugs
- 535:15-10-15 Compounding of non-sterile radiopharmaceuticals

PART 3. GOOD COMPOUNDING PRACTICES FOR STERILE PRODUCTS

- 535:15-10-50 Purpose
- 535:15-10-51 Definitions
- 535:15-10-52 Pharmacist responsibilities
- 535:15-10-53 General requirements
- 535:15-10-54 CSP microbial risk levels
- 535:15-10-55 Drug compounding facilities
- 535:15-10-56 Compounding equipment
- 535:15-10-57 Component selection requirements
- 535:15-10-58 Control of drug product containers
- 535:15-10-59 Drug compounding controls
- 535:15-10-60 Transfer of compounded prescription
- 535:15-10-61 Beyond-use dating
- 535:15-10-62 Labeling
- 535:15-10-63 Records and reports
- 535:15-10-64 Compounding for institution and/or practitioner administration
- 535:15-10-65 Compounding of sterile hazardous drugs
- 535:15-10-66 Compounding of sterile radiopharmaceuticals
- 535:15-10-67 Compounding of sterile allergen extracts