TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY
CHAPTER 15. PHARMACIES

RULEMAKING ACTION:
Notice of proposed PERMANENT rulemaking

PROPOSED RULES:
Subchapter 3. Pharmacies
535:15-3-9. Non-resident pharmacies [AMENDED]
535:15-3-11. Prescription drugs [AMENDED]
535:15-3-12.1. Electronic transfer of prescription refill information [AMENDED]
535:15-3-21. Prescription fill, refill and partial fill records and reports [AMENDED]
Subchapter 5. Hospital Pharmacies
535:15-5-2. Definitions [AMENDED]
535:15-5-7.2. Supervision of pharmacy technicians [AMENDED]
535:15-5-7.3. Auxiliary supportive personnel tasks [AMENDED]
535:15-5-7.4. Pharmacy technician tasks [AMENDED]
Subchapter 10. Good Compounding Practices
535:15-10-52. Pharmacist responsibilities [AMENDED]
PART 5. Handling Hazardous Drugs in a Pharmacy [NEW]
535:15-10-73. Purpose [NEW]
535:15-10-74. Definitions [Reserved] [NEW]
535:15-10-75. Categories of Involvement [NEW]
535:15-10-76. Pharmacy List of Hazardous Drugs [NEW]
535:15-10-77. Responsibilities of Personnel Handling Hazardous Drugs [NEW]
535:15-10-78. Pharmacy and Engineering Controls [NEW]
535:15-10-79. Personal Protective Equipment [NEW]
535:15-10-80. Hazard Communication Program [NEW]
535:15-10-81. Personnel Training [NEW]
535:15-10-82. Receiving and Storage [NEW]
535:15-10-83. Labeling, Packaging, Transport, and Disposal [NEW]
535:15-10-84. Dispensing Final/Finished Dosage Forms [NEW]
535:15-10-85. Compounding, Nonsterile [NEW]
535:15-10-86. Compounding, Sterile [NEW]
535:15-10-87. Deactivating, Decontaminating, Cleaning, and Disinfecting [NEW]
535:15-10-88. Spill Control [NEW]
535:15-10-89. Documentation [NEW]
535:15-10-90. Hazardous Waste [NEW]
535:15-10-91. Medical Surveillance [NEW]
SUBCHAPTER 13. PHARMACY SUPPORTIVE PERSONNEL
535:15-13-5. Supervision of pharmacy technicians [AMENDED]
535:15-13-6. Duties [AMENDED]
535:15-13-7. Prohibited duties [AMENDED]
535:15-13-13. Pharmacy technician training [AMENDED]

SUMMARY:
The revision in 535:15-3-9 (c) (3) adds to non-resident pharmacy rules that no pharmacist
may serve as pharmacist in charge in more than one pharmacy at a time.

The revision in 535:15-3-11 (c) adds the words "shipping to a reverse distributor for" to "destruction or by being returned to the supplier" to clarify the rule.

The revision in 535:15-3-12.1. adds the ability of a permitted technician to do an electronic transfer of prescription refill information where there is a common electronic file.

The three revisions in 535:15-3-21 (d) (1) (C), 535:15-3-21 (d) (2) (A) and 535:15-3-21 (d) (3) correct the CFR cite to CFR 1306.22.

The revision in 535:15-5-2 removes the "Certified pharmacy technician" definition from the hospital pharmacy rules and adds "and direct" after "immediate supervision" in the Pharmacy technician definition.

The revision in 535:15-5-7.2 (a) adds the words "and direct" to supervision of pharmacy technicians.

The revision in 535:15-5-7-2 (e) changes the technician ratio from to not exceed two to five; and adds a reference to the rule regarding technician ratio for sterile compounding which is limited to two technicians per supervising pharmacist.

The revision in 535:15-5-7.3. (a) (2) removes "data entry" from auxiliary supportive (non-technician) tasks and is being moved to technician tasks in 535:15-5-7.4 (a) (13).

The revision in 535:15-5-7.4 (a) (6) (A) – (C) adds that a pharmacy technicians may fill modified unit dose distribution systems, automated dispensing systems and/or unit dose distribution systems, without a final check by the pharmacist, when certain processes, policy and procedures, and controls are in place.

The revision in 535:15-5-7.4 (a) (6) (D) adds the ability for pharmacy technicians to transport non-CDS stock to a licensed drug room to fill an automated dispensing system in certain circumstances.

The revision in 535:15-5-7.4 (a) (10) removes (A) and (B) describing functions/limitations that a pharmacy technician may perform in a hospital pharmacy since these requirements since are replaced with the rule 535:15-10-52 (d).

The revision in 535:15-5-7.4 (a) (10) removes (C) which described functions / limitations that a certified pharmacy technician may perform in a hospital pharmacy since rules are now included in Subchapter 10 compounding rules for sterile products/preparations.

The revision in 535:15-5-7.4 (a) (13) adds data entry to technician tasks.

The revision in Part 3. Good Compounding Practices for Sterile Preparations, 535:15-10-52 (e) adds that the pharmacy technician ratio shall not exceed two technicians for one supervising pharmacist on duty when compounding sterile preparations.

Added is the new Part 5. Handling Hazardous Drugs in a Pharmacy to Subchapter 10 Good Compounding Practices. Rule 535:15-10-73 describes the purpose for the rules for handling hazardous drugs in a pharmacy.

Rule 535:15-10-74 is reserved for definitions.

Rule 535:15-10-75 includes pharmacy rules for categories of involvement for handling hazardous drugs.

Rule 535:15-10-76 includes pharmacy rules for the pharmacy list of hazardous drugs and assessment of risk or containment strategies and work practices.

Rule 535:15-10-77 describe the responsibilities of personnel handling hazardous drugs in and for the pharmacy.

Rule 535:15-10-78 describe required pharmacy and engineering controls regarding hazardous drugs in a pharmacy.
Rule 535:15-10-79 describe personal protective equipment required in a pharmacy for hazardous drugs.

Rule 535:15-10-80 describe requirements for standard operating procedures to ensure worker safety and training during all aspects of hazardous drug handling. These rules describe requirements for hazardous drug communication. These rules describe SOP's for hazardous drug training.

Rule 535:15-10-81 describe training requirements for all personnel regarding hazardous drugs.

Rule 535:15-10-82 describe requirements for the pharmacy standard operating procedure for receiving and storage of hazardous drugs, including requirements if the shipping container appears damaged and/or such damaged container must be opened.

Rule 535:15-10-83 describe the requirements for pharmacies standard operating procedures regarding labeling packaging, transport, and disposal of hazardous drugs.

Rule 535:15-10-84 describe requirements for pharmacies dispensing final / finished dosage form of hazardous drug or hazardous drug products.

Rule 535:15-10-85 describe requirements for pharmacies standard operating procedures regarding labeling packaging, transport, and disposal of hazardous drugs.

Rule 535:15-10-86 describe requirement for pharmacies compounding non-sterile hazardous drugs.

Rule 535:15-10-87 describe requirements for pharmacies compounding sterile hazardous drugs.

Rule 535:15-10-88 describe requirements for pharmacies regarding hazardous drugs regarding deactivating, decontamination, cleaning and disinfecting.

Rule 535:15-10-89 describe documentation in standard operating procedures and requirement for safety data sheets regarding hazardous drugs.

Rule 535:15-10-90 describe rules for disposal of hazardous drug waste and required standard operating procedures.

Rule 535:15-10-91 describe rules for medical surveillance regarding hazardous drugs and follow-up plans.

Rule 535:15-13-5 (c) increases the pharmacy technician ratio to no more than "five" to one supervising pharmacist on duty from "two".

New rule 535:15-13-5 (d) sets a ratio of "two" pharmacy technicians to a supervising pharmacist on duty for compounded sterile preparations.

The old 535:15-13-5 (d) is renumbered to (e).

The old 535:15-13-5 (e) is renumbered to (f).

The revision in 535:15-13-6 (a) (2) removes "data entry" from tasks that can be performed by auxiliary personnel. That duty is moved to technician duties in 535:15-13-6 (b) (10).

The revision removes the pharmacy technician limitations in 535:15-13-6 (b) (7)

The revision renumbers 535:15-13-6 (b) the old (8) to (7).

The revision renumbers 535:15-13-16 (b) the old (9) to (8).

The revision renumbers 535:15-13-6 (b) the old (10) to (9).

The revision in 535:15-13-6 (b) adds (10) data entry and initial order entry of prescriptions.

The revision in 535:15-13-6 (b) (11) adds to technician duties that they may clarify non-CDS prescription. If omitted, the date, quantity, route of administration, and the number of refills may be added to a prescription after confirming with the prescriber or prescriber's authorized agent. Such clarification shall be notated by the technician on the back of the prescription.
The revision in 535:15-13-7 (a) (5) removes the requirement that only the pharmacy may prepare multi-ingredient, non-repetitive, cytotoxic or experimental drug IV's, enteral or other sterile multi-ingredient medication, and the pharmacist shall be responsible for weighing, measuring and calculating ingredients for sterile compounded preparations because these rules for sterile compounding are now in Subchapter 10.

The revisions in 535:15-13-7 (a) (6) through 535:15-13-7 (a) (8) are renumbered to 535:15-13-7 (a) (5) through 535:15-13-7 (a) (7).

The revision in 535:15-13-13 (a) (3) (D) removes "Pharmacy technician applicants shall not have fully received their permits until they have completed Phase II of pharmacy technician training", as that is covered in 535:15-13-13 (a) (3) (C) and (D).

The revision in 535:15-13-13 (e) adds "The annual training must include the pharmacy technician law exam provided by the Board and drug diversion training" to the rule.

AUTHORITY:
Oklahoma State Board of Pharmacy is the regulatory authority under Title 59 O.S., Sec. 353.7, 353.11 - 353.20.1, 353.22, 353.24 - 353.26 - 354, and 367.8.

COMMENT PERIOD:
The comment period will run from February 15, 2019 through March 18, 2019, at 3:00 p.m. Written comments may be sent to the offices of the Board at 2920 N Lincoln Boulevard Suite A, Oklahoma City, OK 73105-4212.

PUBLIC HEARING:
A public hearing will be held to provide an opportunity for persons to orally present their views on March 19, 2019, at 10:00 a.m., in our office at 2920 N Lincoln Boulevard Suite A, Oklahoma City, OK 73105-4212. Written notice of intent to make oral comment must be received by this office no later than March 18, 2019, at 3:00 p.m.

REQUEST FOR COMMENTS FROM BUSINESS ENTITIES:
Business entities affected by these proposed rules are requested to provide the Board, within the comment period, in dollar amounts if possible, the increase in the level of direct costs such as fees and indirect costs such as record keeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred due to compliance with the proposed rule(s).

COPIES OF PROPOSED RULES:
Proposed rules are available for review in our office at 2920 N Lincoln Boulevard Suite A, Oklahoma City, OK 73105-4212. Copies may be viewed in our offices or on our website www.pharmacy.ok.gov, or provided at a cost of 25 cents per page.

RULE IMPACT STATEMENT:
A rule impact statement will be prepared and will be available on and after February 15, 2019, at the location listed above for copies of the proposed rules. It may be viewed in our office, on our website, or copies may be obtained for 25 cents per page.

CONTACT PERSON:
Dorothy Gourley, Executive Director, Oklahoma State Board of Pharmacy located at 2920 N Lincoln Boulevard Suite A, Oklahoma City, OK 73105-4212. The Board phone number is (405) 521-3815 and the FAX number is (405) 521-3758.