TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY
CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS

RULEMAKING ACTION:

PERMANENT final adoption

RULES:

Subchapter 1. General Requirements
535:25-1-1. Purpose [AMENDED]
Subchapter 3. Applicants, Registrants, and Applications [AMENDED]
535:25-3-3. Qualifications and requirements for registrant applicants [AMENDED]
535:25-3-4. Requirements for applicants or registrants who have had Board action taken against any license, permit or certificate [AMENDED]
535:25-3-5. Multiple licenses / permits [AMENDED]
535:25-3-7. Change requirements and notification [AMENDED]
535:25-3-8. Requirements for Licensees [NEW]
Subchapter 5. General Requirements or Procedures
535:25-5-1. Inspector's warning notice [AMENDED]
535:25-5-3. Drug Screening [AMENDED]
535:25-5-5. Prescription drug (Rx only) purchases and record requirements [AMENDED]
Subchapter 6. Post-Military Service Applicants [NEW]
535:25-6-3. Post-Military Service Applicants [NEW]
Subchapter 7. Rules of Registrant Conduct
535:25-7-3. Registrant Conduct [AMENDED]
535:25-7-4. Confidentiality [AMENDED]
535:25-7-5. Practice of medicine [AMENDED]
535:25-7-6. Governing body [AMENDED]
Subchapter 9. Violations of the rules of registrant conduct
535:25-9-1. Scope and purpose [AMENDED]
535:25-9-3. Violating laws or rules [AMENDED]
535:25-9-4. False report or record, billing incorrectly, fraudulent billing or reports [AMENDED]
535:25-9-8. Failure to maintain effective controls [AMENDED]
535:25-9-9. ~~Misfiling~~ Misfill or incorrect fill of a prescription or drug order [AMENDED]
535:25-9-10. Patient Health and Safety [NEW]
535:25-9-11. Arrangements [NEW]
535:25-9-12. Professional fee [NEW]
535:25-9-13. Auto Refills [NEW]

AUTHORITY:

Oklahoma State Board of Pharmacy is the regulatory authority under Title 59 O.S., Sec. 353.7, 353.13, 353.13A, 353.16A, 353.17, 353.18, 353.20, 353.22, 353.24 - 353.26, 353.29, 354, and 367.8; Title 51 OS 24A et seq.; Title 75 OS, Sec 2-201, 2-208, and 2-210.

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n/a

ANALYSIS:

The revision in 535:25-1-1 corrects grammar, clarifies the rule, removes the old (d) as well as renumbers the subsections that follow. The revision in 535:25-3-3, 535:25-3-4 and 535:25-3-7 standardize Board reference, improve grammar and clarity of the rules; make changes due to the new federal drug quality and security act; and they change parenteral to sterile compounding.

The revision in 535:25-3-5 modified the multiple license and permits section, 535:25-3-7 modifies requirements and notices at change; and it clarifies the requirement that a new license must be issued prior to drugs being moved to or stored at a new address; the changes improve grammar and clarity of the rule. Requirements for licensees are added at 535:25-3-8.

The revision in 535:25-5-1 change inspector warning notices. Revisions in 535:25-5-3 535:25-5-5, 535:25-7-3, 535:25-7-4, 535:25-7-6, and 535:25-7-6 improve the grammar, punctuation and clarity of these rules; and they standardize Board references. A new 535:25-6-3 rule is added regarding post-military service applicants. The revision in 535:25-7-5 expands prohibition to mid-level practitioners.

Revisions in 535:25-9-1 corrects the scope and purpose statement. Revisions in 535:25-9-3 standardized Board and Oklahoma and federal law references. Revisions in 535:25-9-4 correct grammar, punctuation, and clarify the rules. The revision in 535:25-9-8 improve grammar and change the rules regarding effective controls and violations of registrant conduct. The change in 535:25-9-9 corrects the grammar on the rule. Added in 535:25-9-10 are rules regarding patient safety, while revised in 535:25-9-11 are rules regarding arrangements inimical to public health; 535:25-9-12 regarding professional fee and 535:25-9-13 regarding auto refills.

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PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTION 250.3(5) AND 308(E), WITH AN EFFECTIVE DATE OF AUGUST 27, 2015.

ATTESTATION

I, the undersigned, do hereby attest that the copy enclosed herewith is a true and correct copy of amendments to **CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS**
which were considered finally adopted by the Oklahoma State Board of Pharmacy on June 8, 2015, under permanent rulemaking provisions of the Administrative Procedures Act, 75 O.S., Sections 250 et seq.

I, the undersigned, do hereby attest that such rules were finally adopted in substantial compliance with the Administrative Procedures Act.

_____

John A. Foust, Attestation Officer
Executive Director
Oklahoma State Board of Pharmacy

June 12, 2015

TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY
CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS

SUBCHAPTER 1. GENERAL REQUIREMENTS

535:25-1-1. Purpose

(a) The rules of this Chapter regulate the sale of drugs, medicines, chemicals and poisons in order to ~~and~~ prevent illegal diversion of dangerous drugs.

(b) The rules of this Chapter ~~further~~ describe requirements applicable ~~and exclusions referring~~ to various registrants.

(c) The rules of this Chapter describe an inspector's notice to registrants to correct deficiencies and give notice of compliance.

(d) ~~The rules of this Chapter describe the method which registrants must use to formally lift the suspension and/or probation from their license, permit, and/or certificate.~~

~~(e)~~ The rules of this Chapter describe minimum qualifications and requirements for all applicants and registrants.

(e) ~~(f)~~ The rules of this Chapter describe registrant conduct and violations of registrant conduct.

SUBCHAPTER 3. APPLICANTS, REGISTRANTS, AND APPLICATIONS

535:25-3-3. Qualifications and requirements for registrant applicants

(a) The Board shall consider at least the following factors in reviewing the qualifications of registrants or applicants for licensure e.g.:

(1) Any charges, convictions, receipt of deferred sentence or deferred prosecution, or pleading of no contest of the applicant or registrant under any federal, state, or local laws relating to drug samples, drug distribution, or distribution of controlled substances;

(2) Any felony charges, convictions, receipt of deferred sentence or deferred prosecution, or pleading of no contest of the applicant or registrant under federal, state, or local laws;

(3) The applicant's or registrant's past experience with prescription drugs, including controlled substances;

(4) The furnishing by the applicant or registrant of fictitious, false, misleading, or fraudulent material in any application (original, new or renewal) or failing to provide information relevant to this application;

(5) The suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant or registrant;

(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 by rule and law ~~under this section~~;

(8) Abuse of alcohol or habit-forming drugs, or use of illegal CDS drugs or positive drug screen for such illegal substance or its ~~its'~~ metabolite;

(9) Practicing as a registrant without reasonable skill and safety by reason of use and/or abuse of drugs, narcotics, chemicals or any other type of material, or as a result of any mental or physical condition; and,

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

(b) The applicant shall be forthright and open in the provision of information to the Board in the application process. No license, permit or certificate shall be awarded to an applicant who does not provide the Board with complete open and honest responses to all requests for information.

(c) The applicant shall be candid in regards to providing information related to any academic misconduct, malpractice, legal, or disciplinary action.

(d) The applicant shall fully and completely disclose ownership of any pharmacy, wholesaler, distributor, manufacturer, repackager, ~~packager~~,third-party logistics provider, outsourcing facility, medical gas supplier or medical gas distributor or any other person licensed by the Board. ~~under Title 59 O.S. Section 353.18.~~
(e) The Board shall have the right to deny a license to an applicant or registrant if it determines that the granting of such a license would not be consistent with the public health and safety.

535:25-3-4. Requirements for applicants or registrants who have had Board action taken against any license, permit or certificate
(a) If the Board approves an application of 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 year probation.~~

~~(2) Any~~ any specific requirements placed on the applicant by the Board based on the previous action, or pending action, and applicant's or registrant's current status.

(b) ~~(3)~~ Any subsequent 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.
(c) ~~(4)~~ Failure of the applicant or registrant to meet any terms or requirements of the
Board shall subject the applicant or registrant to Board action based on current failure and previous Board action against an applicant or a registrant ~~previous~~ license. ~~License~~
(d) ~~(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.

535:25-3-5. Multiple licenses / permits
(a) **Pharmacy, ~~and~~ Manufacturer, Repackager ~~Packager~~, ~~or~~ Wholesaler, Distributor or Third-party logistics provider**. A ~~There shall be no multiple licensing that would include a~~ pharmacy shall not be licensed in the same location as ~~and~~ a manufacturer, ~~or~~ repackager, ~~packager or wholesaler~~ wholesale distributor or third party logistics provider ~~in the same location~~.
(b) **Pharmacy/Pharmacy.** No more than one pharmacy license will be allowed in one location.
(c) **Wholesaler/Wholesaler.** ~~More~~ No more than one wholesale distributor license will ~~not~~ be allowed in one location.
(d) **Wholesaler/Repackager ~~Packager~~**. The licensing of a wholesaler distributor and a repackager ~~packager~~ in the same location will be allowed.
(e) **Pharmacy/Drug Supplier**. The licensing of a pharmacy license and pharmacy drug supplier permit in the same location will be allowed.
(f) **Pharmacy / Outsourcing Facility**. The licensing of a pharmacy and an outsourcing facility will be allowed when state and federal requirements are met.
(g) **Pharmacy/Sterile compounding ~~Parenteral~~**. The licensing of a pharmacy and a sterile compounding ~~parenteral~~ pharmacy ~~permit~~ in the same location will be allowed.
~~(g)~~ (h) **Intern/Technician.** Applicants may not hold an intern license and a technician permit at the same time.
~~(h)~~ (i) **Pharmacist/Technician.** Applicants may not hold a pharmacist license and a technician permit at the same time. A pharmacist who has had Board action taken against his pharmacist license for whatever reason and no longer holds a current pharmacist license is not eligible for a technician permit.

535:25-3-7. Change requirements and notification
(a) Change of name, ownership, and/or location shall require a new license for ~~on~~ all business permits, certificates or licenses (e.g. pharmacy, wholesale distributor ~~wholesaler~~, repackager ~~packager~~, manufacturer, outsourcing facility, third-party logistics provider, medical gas supplier and distributor, training areas, sterile

compounding ~~parenteral~~, drug supplier, etc.)

(1) A change of ownership occurs when:

(A) ~~the original owner(s) transfers 20% or more of the ownership of the entity owning the license, permit or certificate to another owner;~~

~~(B)~~ a change of 20% or more of the ownership of the entity owning the license, permit or certificate occurs (for example, when the corporation owning the license, permit or certificate sells 20% or more of the stock); or

(B) ~~(C)~~ a change of ownership form occurs (for example, from a sole proprietor ownership to a partnership, limited liability company or corporation).

(2) Any ownership change not reported as a change of ownership because it involves a transfer of less than 20% of the ownership of the entity owning the license, permit or certificate must be reported at the next renewal of the entity license, permit or certificate.

(3) For publicly traded corporations, a routine sale of stock is not a change of ownership. (Note: a publicly traded corporation is a corporation owned by stockholders who are members of the general public and who trade shares publicly, often through a listing on a stock exchange.)

(b) Changes:

(1) Changes of ownership, name, and/or location ~~will~~ require a new license, special inspection and special inspection fee.

(2) All changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. for businesses the address, manager, contact person, phone, etc. and/or for individuals name, address, etc.)

(3) Address change requires a new license prior to drugs being moved or stored at the new address, see (1) above.

(c) Every applicant for change or renewal of license, permit or certificate shall meet the requirements in 535:25 at a minimum.

~~(d) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. for businesses the manager, contact person, phone, etc. and/or for individuals name, address, etc.)~~

535:25-3-8. Requirements for Licensees

(a) Licensees shall sell, ship, deliver, etc. only to the address listed on the receiving licensee's license.

(b) Licensees that store, ship, sell, deliver, or handle drugs shall not operate from a place of residence

(c) Licensees shall not receive drugs at other than the address listed on their license.

SUBCHAPTER 5. GENERAL REQUIREMENTS OR PROCEDURES

535:25-5-1. Inspector's warning notice

(a) **Purpose.** An inspector's warning notice protects public health by allowing registrants to expeditiously correct violations of laws and rules, and report these corrections to the Board in writing.

(b) **Recipient.** A warning notice may be issued to any registrant found to be violating the rules of this Title (OAC 535), ~~Oklahoma Statutes, Title~~ 59~~,~~ O.S. Section 353 et seq., and/or any federal, state or ~~and~~ local laws and rules.

(c) **Issuance.** An inspector may issue a warning notice at the time a violation is found.

(d) ~~**Filing.** The warning notice shall become an integral part of a file.~~

~~(e)~~ **Failure to respond.** A recipient's failure to satisfactorily respond within ten days to a warning notice may be referred by the Director to the Board for review or complaint and hearing.

(e) ~~(f)~~ **Board review of ~~two~~ warning notices.** Any registrant receiving a ~~two or more~~ warning notice ~~notices within a twelve-month period~~ may be referred by the Director to the Board for review or complaint and

hearing.

535:25-5-3. Drug Screening

(a) Any individual registrant who is suspended and/or placed on probation may be required to submit to random drug screening.

(b) Random drug screening required by the Board shall ~~will~~ be done at the registrant's expense.

535:25-5-5. Prescription drug (Rx only) purchases and record requirements

(a) All registrants shall keep adequate records to assure that prescription drugs are legally received and/or distributed or dispensed, as appropriate. Such records shall include, but not be limited to, all prescription drug purchase (e.g. invoices, etc.) and inventory records and shall be maintained and be readily retrievable for a period of at least 2 years.

(b) Prescription drug purchases may only be made from entities licensed to sell prescription drugs. A registrant shall exercise professional judgment regarding the purchase of prescription drugs in order to assure a safe, sanitary and legal prescription drug supply is maintained.

SUBCHAPTER 6. POST-MILITARY SERVICE APPLICANTS

535:25-6-1. [RESERVED]

535:25-6-2. [RESERVED]

535:25-6-3. Post-Military Service Applicants

(a) The Board shall consider the equivalent education, training and experience completed by an applicant for licensure while the applicant was a member of the United States Armed Forces or Reserves, National Guard of any state, the Military Reserves of any state, or the Naval militias of any state, and apply it in the manner most favorable toward satisfying the qualifications for issuance of a license or approval for license examination.

(b) The Board shall expedite the process of licensure by reciprocity for applicants whose spouse is an active duty member of the Armed Forces of the United States if:

(1) the military service member is on active duty within Oklahoma or claims permanent residency within Oklahoma for the six (6) months prior to assignment to active duty or during the period of active duty; and,

(2) the applicant left employment in another state to accompany the military service member spouse to Oklahoma.

SUBCHAPTER 7. RULES OF REGISTRANT CONDUCT

535:25-7-3. Registrant conduct

(a) Registrants shall ~~will at all times~~ conduct business in conformity with all federal, state and municipal laws at all times.

(b) Registrants shall conduct themselves at all times in a manner that will entitle them to the respect and confidence of the community in which they practice.

(c) Abuse of ~~Registrants shall not abuse~~ alcohol or drugs, ~~nor shall they~~ use of an illegal or controlled dangerous ~~CDS~~ substance, or testing ~~nor test~~ positive for such substance or its ~~its'~~ metabolite is a violation of registrant conduct.

535:25-7-4. Confidentiality

A registrant shall ~~will~~ hold the health and safety of his ~~their~~ patrons as his ~~their~~ first consideration and will not divulge the nature of the patrons' problems or ailments or any confidence entrusted to him ~~them~~ in his ~~their~~ licensed capacity except in response to legal requirements or in the best interest of the patron.

535:25-7-5. Practice of medicine

Registrants will refrain from any attempt at diagnosis or treatment that is the legally constituted right or obligation of any licensed practitioner or mid-level practitioner ~~of the healing arts~~.

535:25-7-6. Governing body

(a) A registrant will recognize the ~~State~~ Board ~~of Pharmacy~~ as the governing body in the
State of Oklahoma and report to them any violation of pharmacy laws or regulations that may come to his ~~their~~ attention.

(b) A registrant who fails to report such violations will be subject to Board action against his ~~their~~ license, permit or certificate.

SUBCHAPTER 9. VIOLATIONS OF THE RULES OF REGISTRANT CONDUCT

535:25-9-1. Scope and purpose

The rules of this subchapter describe some violations of the rules of registrant conduct. Violations of registrant ~~professional~~ conduct include, but are not limited to, those violations described in this subchapter.

535:25-9-3. Violating laws or rules

A registrant shall not violate directly, (or indirectly, through actions of another), assist or abet in the violation of, or conspire to violate, any provision of the Oklahoma Pharmacy Act, ~~Title~~ 59, O.S. Section 353 et seq., the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security Act of 2013, the Prescription Drug Marketing Act (21 U.S.C., Sec. 331 et seq.), the Robinson-Patman Act (15 U.S.C., Sec. 13 et seq.), or federal, state and local laws and rules.

535:25-9-4. False report or record, billing incorrectly, fraudulent billing or reports

The following are violations of registrant conduct:

(1) Making or filing a ~~A~~ report or record which a registrant knows or should have known to be false, intentionally or negligently failing to file a report or record required by federal, state or local laws or rules, willfully impeding or obstructing such filing, or inducing another person to violate this rule ~~do so~~. Such reports or records include only those which the registrant is required to make or file in his capacity as a registrant;

(2) Billing or charging for quantities greater than delivered, or for a brand when a generic is dispensed~~.~~;

(3) Fraudulent billing or submitting false reports to a third party payer of prescription drugs.

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

The following are violations of registrant conduct:

~~(a)~~ (1) Failure to establish and maintain effective controls to prevent prescription errors; ~~is a violation of registrant conduct.~~

~~(b)~~ (2) Failure to establish and maintain effective controls against the diversion of prescription drugs and/or controlled dangerous 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)~~ (3) The sale of dangerous drugs to a person or entity not eligible to receive such drugs; ~~is a violation~~

~~of registrant conduct.~~

~~(d)~~ (4) The purchase of dangerous drugs from a person or entity not eligible to possess such drugs; ~~is a violation of registrant conduct.~~

~~(e)~~ (5) Failure ~~Failing~~ to establish and maintain suspicious order monitoring records in a suspicious order monitoring program; and failure to notify the Board of confirmed suspicious orders; .

~~(f)~~ (6) Shipping ~~It is a violation to ship~~ orders that are confirmed as suspicious; and, ~~.~~

(7) Shipping to other than the licensees address on the license.

535:25-9-9. ~~Misfiling~~ Misfill or incorrect fill of a prescription or drug order

The incorrect fill or misfill of ~~Misfilling~~ of a prescription or drug order which departs from the standards of care ordinarily exercised by a registrant with proof of actual injury not having to be established is a violation of registrant conduct.

535:25-9-10. Patient health and safety

The health and safety of patients shall be a registrant's first consideration

535:25-9-11. Arrangements

Registrants shall oppose any arrangements inimical to public health. Such an arrangement could include, but is not limited to, an arrangement between a registrant and a prescriber or any practitioner of the healing arts whereby fees are divided or in which private formulas are concerned.

535:25-9-12. Professional fee

A registrant's fee for professional services shall be fair, equitable, and commensurate with the knowledge and skill required to compound and dispense prescriptions and/or to render other professional services.

535:25-9-13. Auto refills

A registrant shall not do auto refills of a prescription unless authorized to do so by the patient or the patient's agent.