

TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY

CHAPTER 1. ADMINISTRATIVE OPERATIONS

RULEMAKING ACTION:

PERMANENT final adoption

RULES:

Subchapter 1. General Provisions

535:1-1-1. Purpose [AMENDED]

Subchapter 3. Description of organization

535:1-3-1. Creation of Board [AMENDED]

535:1-3-2. Board members [AMENDED]

535:1-3-3. Powers and duties of Board [AMENDED]

Subchapter 5. ~~Board Administrative~~ ~~General course in method of~~ Operations

535:1-5-1. Board office [AMENDED]

535:1-5-3. Communication in writing [AMENDED]

535:1-5-4. Board meetings [AMENDED]

535:1-5-5. Appearance before the Board ~~Complaints~~ [AMENDED]

535:1-5-5.1. Complaint confidentiality [AMENDED]

535:1-5-6. Availability of records [AMENDED]

Subchapter 7. Individual proceedings

535:1-7-1. Complaints [AMENDED]

535:1-7-2. Serving of notices [AMENDED]

535:1-7-3. Hearings [AMENDED]

535:1-7-3.1. Standard of proof [AMENDED]

535:1-7-4. Failure to appear or failure to comply [AMENDED]

535:1-7-5. Subpoenas [AMENDED]

535:1-7-6. Hearing records and record maintenance [AMENDED]

Subchapter 8. Requests for rule changes [NEW]

535:1-8-1. Requests for rule changes [NEW]

Subchapter 9. Rulemaking hearings

535:1-9-1. Reasonable opportunity for public input on proposed rulemaking [AMENDED]

535:1-9-2. Administrative Procedures Act (APA) rulemaking requirements [AMENDED]

Subchapter 11. Fees

535:1-11-1. Annual licenses, permits and renewals [AMENDED]

535:1-11-2. Pharmacist initial registration and other fees [AMENDED]

535:1-11-4. Other fees [AMENDED]

535:1-11-5. Miscellaneous [AMENDED]

Subchapter 13. Requests for rule changes [REVOKED]

535:1-13-1. Requests for rule changes [REVOKED]

Subchapter 15. Declaratory rulings

535:1-15-1. Definitions [AMENDED]

535:1-15-2. Declaratory rulings [AMENDED]

AUTHORITY:

Oklahoma State Board of Pharmacy is the regulatory authority under Title 59 O.S., Sec. 353.3, 353.5 - 353.7, 353.9, 353.11, 353.18; 353.20, 353.22, 353.24 - 353.26, 353.29, 353.30; and Title 75 O.S., Section 302, 305, 307, and 309; and Title 63 O.S., Sec 2-201, 2-208 and 2-210; and Title 51 Sec. 24 A.5 (3)

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n/a

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n/a

ANALYSIS:

The revisions in 535:1-1-1 removes archaic language, standardizes 'Board' references and corrects grammar. The revisions in 535:1-3-1, 535:1-3-2, 535:1-3-3, 535:1-5-1, 535:1-5-3, 535:1-5-4, and 535:1-5-6(a) cleans up law cites and standardizes "Board of Pharmacy to "Board". The revisions in 535:1-5-1 also corrects the Board address to 2920 N Lincoln Suite A, Oklahoma City, OK 73105-4212. The revisions in 535:1-5-3, 535:1-7-2 corrects "Executive Director of the Board" to "Director". The revisions in 535:1-5-4(d) correct grammar. The revisions in 535:1-5-5 correct title and describes the process for appearances before the Board.

The revision in 535:1-5-5.1 cleans up language in (b), the revision in 535:1-5-6 clarifies official records, in 535:1-7-1 clarifies sworn complaint and notice of hearing; the revisions in 535:1-7-2(b) clarifies service of notice; and in 535:1-7-3 clarifies notice time and continuance, imminent danger suspension, and the hearing procedure. The revisions in 535:1-7-3.1 clarify standard of proof. The revisions in 535:1-7-4, in 535:1-7-5 and 535:1-7-6 clarify these rules.

The new rule in 535:1-8-1 was moved from 535:1-13-1 as this rule better fits between subchapter 7 and 9. The revisions in 535:1-9-1 and 535:1-9-2 clarify the rules and cleanup law cites.

The revisions in 535:1-11-1 clean up the titles in (5), (7), (8), (9), (10), (11), added are the fees for two new category fees for entities created under federal law called "Outsourcing facility" (12) and "Third-party logistics provider" (13). These new fees are authorized under Title 59 OS 353.18. Federal requirements on the state for these entities require separate rules. The old 535:1-11-1 (12) and (13) are moved to (14) and (15) respectively.

The revisions in 535:1-11-2 (b) (1) and (2) move 535-1-11-5 (2) and (5) up to this fee section for pharmacist for clarity. The revisions in 535-1-11-4 do not change fees, they just update from tape to recording in (b) (6) and cleanup language regarding website information in (c).

The revision in 535-1-11-5 deletes (2) and (5) which are moved for clarity to 535:1-11-2 (b) (1) and (2) and renumbers the contents of the section. Rules in 535:1-13 are revoked and the text is moved to 535-1-8 as these rules better fit between subchapter 7 and 9. The revisions in 535:1-15-1 and 535:1-15-2 improve the clarity of the declaratory ruling rules.

CONTACT PERSON:

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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 1. Administrative Operations** 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 1. ADMINISTRATIVE OPERATIONS**

SUBCHAPTER 1. GENERAL PROVISIONS

535:1-1-1. Purpose

(a) The rules of this Chapter describe the organization ~~and, the general course in method of operations, the administrative operation of the Board,~~ the procedures and practices at individual proceedings, the practices at rulemaking hearings, the procedures for requests for rule changes and the procedures for the filing and prompt disposition of petitions for declaratory rulings as to the applicability of any rule or order of the Board of Pharmacy as required under the Administrative Procedures Act.

(b) The fee schedule of this Chapter provides the public and registrants ~~registrant~~ access to records, information and fees as required or suggested by the Open Records Act.

SUBCHAPTER 3. DESCRIPTION OF ORGANIZATION

535:1-3-1. Creation of Board

(a) The State Board of Pharmacy is created by virtue of Article 5, Section 39 of the Constitution of Oklahoma. Statutes relating thereto are found in the Oklahoma Pharmacy Act, ~~Title 59, Section~~ Sections 353 et seq. of the Oklahoma Statutes.

(b) Unless otherwise stated, as used herein, Board means Board of Pharmacy.

535:1-3-2. Board members

The Board of Pharmacy shall consist of six (6) members who are qualified and appointed in accordance with the provisions of 59 O.S., Section 353.3.

535:1-3-3. Powers and duties of Board

The powers and duties of the ~~State Board of Pharmacy~~ are set forth in the Oklahoma Pharmacy Act ~~(the "Act") Statutes of Oklahoma, 59 O.S., Section~~ Sections 353 et seq.

SUBCHAPTER 5. ~~BOARD ADMINISTRATIVE~~ ~~GENERAL COURSE IN METHOD OF OPERATIONS~~

535:1-5-1. Board office

The office of the ~~Oklahoma State Board of Pharmacy~~ is in the Bryan H. Potter Oklahoma State Board of Pharmacy Building, 2920 North Lincoln Boulevard, Oklahoma City, Oklahoma.

535:1-5-3. Communication in writing

Every communication in writing to the Board shall be addressed to the ~~Executive Director of the Board~~ at the Board's principal office, unless the Board directs otherwise.

535:1-5-4. Board meetings

(a) The Board shall hold at least one regular meeting in each calendar year, and at least one meeting for examinations each calendar year.

(b) The Board shall hold other meetings as it deems necessary at the Office of the Board in Oklahoma City, Oklahoma, or such other location as the Board desires.

(c) Special meetings may be called by the President and Director ~~of the Board~~, or a majority of the Board.

(d) Four (4) members of the Board constitute a quorum and may transact any business or hold any hearing by

simple majority vote of a the quorum.

(e) The Board president shall vote only in the case of tie.

535:1-5-5. Appearance before the Board Complaints

All persons desiring to appear before the Board ~~for the purpose of registering a complaint of any nature and/or~~ for any purpose must first furnish the Board with a copy of said information complaint, and/or explanation of the purpose in writing, either in longhand or typewritten, ten (10) days prior to the next regularly scheduled Board meeting in order that they ~~it~~ may be placed on the agenda and a time allocated for discussion.

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 and ~~or~~ informant information provided in conducting its investigations; ~~The Board and~~ may use this information in cases filed against registrants.

(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.

535:1-5-6. Availability of records

(a) **Document location.** All rules and other written statements of policy or interpretations formulated, adopted or used by the Board ~~of Pharmacy~~ in the discharge of its functions and all final orders, decisions and opinions will be made available for public inspection at the principal office during regular office hours.

(b) **Official records.** Copies of official records of the Board ~~of Pharmacy~~ may be made, and certified to by the Director or his designee according to with the fee schedule enacted by the Board. Any ~~material in the Board records or material in the Board's offices of Pharmacy~~ protected from disclosure publication by state law shall not be released.

SUBCHAPTER 7. INDIVIDUAL PROCEEDINGS

535:1-7-1. Complaints

(a) **Sworn complaint.** In every individual proceeding, ~~whether initiated by the Board of Pharmacy or by other complainants, there~~ a sworn complaint shall be filed a sworn complaint naming the person against whom relief is sought and containing a brief statement of the factual allegations and alleged violations with the Director of the Board containing a brief statement setting forth the allegations and naming the person against whom relief is sought.

(b) **Notice of hearing Citation.** The Director ~~of the Board~~ shall issue a notice of hearing citation thereby notifying the person named in the complaint of said filing and the date, time and the place for the hearing. The notice should comply with the requirements of 75 O.S. ~~1971 supp.~~ Section 309 or its successor.

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 mail to the respondent at the last address provided to the Board by respondent or to respondent's attorney.

(b) **Service of notice.** Such service shall constitute proper service ~~be complete~~ upon the personal service or certified mailing of the notice or other paper.

535:1-7-3. Hearings

(a) **Notice time; continuances.** The time set for a hearing, specified in the notice, shall not be less than ten (10) days after the date of the notice. Written motions for any continuances or extensions of time shall state the time desired and the reasons for the

request, and shall be filed with the Board at least five (5) business days before the hearing, and may be denied by the Director ~~of the Board~~ if not filed at least (five) 5 business days before the hearing. ~~The Board hereby authorizes the Director of the Board is authorized to rule on said motions. Said application shall be served upon the Director of the Board and be acted upon promptly by the Director; if~~ is authorized to rule on said motions. ~~if~~ Said application shall be served upon the Director of the Board and be acted upon promptly by the Director; if ~~the motion for continuance or extension is denied; the party may renew the request and make a proper showing for continuance at the hearing.~~

(b) **Imminent Danger Suspension.** If the Director finds that there is imminent danger to the public health or safety, he ~~or she~~ may immediately suspend any registration simultaneously with the scheduling of a Board hearing.

(1) **Method.** The registrant shall be notified of such suspension through an imminent danger letter signed by the Director.

(2) **Notice.** Notice shall be given in the manner described in 535:1-7-2.

(c) **Order of procedure.** Hearings ~~The hearing~~ shall be conducted in an orderly manner by the President of the Board, or his designee. The order of procedure shall will follow that which applies in civil proceedings of Law. However, the rules of evidence shall be those specified by the Oklahoma Administrative Procedures Act.

(d) **Admissibility.** The President of the Board, or his designee, shall rule upon the admissibility of evidence and objections thereto, and shall rule upon other motions or objections arising in the course of the hearing.

535:1-7-3.1. Standard of proof

The standard of proof in an individual proceeding ~~or administrative hearing~~ before the Board is that of clear and convincing evidence.

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

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

(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~~ or his designee. 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 to make an affirmation or to answer a question put to him in the course of a ~~the~~ hearing, ~~the Director of the Board may institute appropriate~~ appropriate judicial proceedings may be instituted 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 hearing shall proceed, so far as it is possible, but the Board, in its discretion, at any time, may continue the ~~proceeding~~ proceedings for such time as may be necessary to secure a final ruling in the ~~judicial compliance proceeding~~ proceedings.

535:1-7-6. Hearing records and record maintenance

(a) **Recordings.** ~~A record by means of tape recording or shorthand notes will be made of all hearings conducted by the Board of Pharmacy unless the presiding officer designates otherwise. (1) Oral proceedings during The Board's Board~~ hearings shall be electronically recorded.

~~(1)-(A)~~ The ~~recording record~~ of the hearing and the file containing the pleading will be maintained in the Board Office. ~~(B)~~ Such record shall be maintained for such time as to protect the record through judicial review.

(2) ~~A copy~~ Copies of the ~~recording recordings~~ of the ~~hearing proceedings~~ shall be provided by the Board agency at the request of any party to the ~~hearing proceedings~~.

(b) **Transcription costs.** The costs of transcription of the ~~recording of a hearing recordings~~ shall be borne by the party requesting the transcription. A transcript of the ~~hearing proceedings~~ shall not be made by the Board except upon written application and a deposit sufficient ~~in the amount~~ to pay for having the ~~recording record~~ transcribed.

(c) **Judicial review.** Electronic recordings of an individual proceeding, as certified by the ~~Director agency~~, may be submitted to the reviewing court by the agency as part of the record of the proceedings under review. In such case where the reviewing court requires transcription, the expense of ~~transcription~~ transcriptions shall be paid by the non-prevailing party.

(d) **Court reporter.** Parties to any Board hearing may have the proceedings transcribed by a court reporter at their own expense.

SUBCHAPTER 8. REQUESTS FOR RULE CHANGES

535:1-8-1. Requests for rule changes

(a) All interested persons may request the Board to promulgate, amend or repeal a rule.

Requests are to be made in writing and filed with the Director. Each request shall set forth fully the reasons for its submission; the alleged need or necessity therefor; whether or not the proposal conflicts with any existing rule, and what, if any, statutory provisions are involved.

(b) Each request to the Board to promulgate, amend or repeal a rule, shall be considered by the Board.

(c) After consideration of a request to promulgate, amend or repeal a rule the Board may:

(1) approve the proposed change in compliance with the Oklahoma Administrative Procedures Act; or,

(2) determine that the proposal or request is not a necessary rule, amendment or repeal; refuse the same and reflect the decision in the regular minutes of the Board.

SUBCHAPTER 9. RULEMAKING HEARINGS

535:1-9-1. Reasonable opportunity for public input on proposed rulemaking

Prior to the adoption, amendment, or repeal of any rule, the Board shall afford any interested person a

reasonable opportunity to submit data, views, or arguments, orally or in writing, to the Board concerning the proposed action on the rule. ~~Should the proposed action on a rule affect one's substantive rights, the opportunity for an oral hearing will be granted if requested in writing by an individual or by an association. If no substantive rights are involved, the opportunity for oral arguments or view is in the discretion of the Board. The Board shall decide whether any substantive rights are involved.~~

535:1-9-2. Administrative Procedures Act (APA) rulemaking requirements

In any rule-making action, the Board shall comply with the then current requirements in the Oklahoma Administrative Procedures Act. ~~(75 O.S. Sec. 301 et seq.)~~

SUBCHAPTER 11. FEES

535:1-11-1. Annual licenses, permits and renewals

Annual license, permit and renewal fees, as set by the Board, shall be as follows:

- (1) Pharmacist renewal (active or inactive) - \$100
- (2) Senior inactive pharmacist renewal (age 65 or over, retired) - \$20
- (3) Pharmacy license
 - (A) Retail, hospital, non-resident, and remote medication order processing - \$150
 - (B) Charitable clinic - \$ 75
 - (C) Hospital drug room - \$ 40
- (4) Oklahoma licensed pharmacy emergency medication kit placed in an Oklahoma Facility [59 O.S. 367.8 (C)] remote site - \$50
- (5) Sterile compounding Parenteral permit - \$ 75
- (6) Drug supplier permit - \$ 20
- (7) Wholesale distributor license ~~Wholesaler permit~~ - \$200
- (8) Repackager license ~~Packager permit~~ - \$200
- (9) Manufacturer license ~~permit~~ - \$200
- (10) Medical gas supplier license ~~permit~~ - \$100
- (11) Medical gas distributor license ~~permit~~ - \$200
- (12) Outsourcing facility license - \$200
- (13) Third-party logistics provider license - \$200
- ~~(12)~~ (14) Pharmacy technician permit - \$40
- ~~(13)~~ (15) Duplicate renewal receipt, permit, or practical experience certificate:
 - (A) Duplicate for lost, destroyed or damaged original-\$10
 - (B) Duplicate or multiple location copy - \$10

535:1-11-2. Pharmacist initial registration and other fees

(a) Pharmacist initial registration fees, as set by the Board, shall be as follows:

- (1) Registration by reciprocity - \$200
- (2) Registration by examination - \$125 + the examination cost
- (3) Registration by score transfer - \$200

(b) Other fees

- (1) Duplicate certificate of registration - \$30
- (2) Pharmacist Reinstatement: Back fees + CE + 15 hours CE penalty + \$100

535:1-11-4. Other fees

(a) For all records required to be open by the Oklahoma Open Records Act, fees shall be charged for copying as

specified in the open records act.

(b) Other fees shall be as follows:

- (1) Registrant computer address disk or e-mailed file:
 - (A) Facility (wholesaler, packager, manufacturer) - \$50
 - (B) Pharmacy - \$75
 - (C) Technician - \$100
 - (D) Intern - \$100
 - (E) Pharmacist - \$100
- (2) Photostat copies, per page - \$.25
- (3) Facsimile (Fax) fee, per page - \$1
- (4) Annual subscriptions (7/01 – 6/30 each year)
 - (A) Notification of rulemaking intent - \$18
 - (B) OSBP/NABP Quarterly Voluntary Compliance Newsletter for other than Oklahoma licensed ~~registered~~ Pharmacists - \$25
 - (C) Board meeting agenda notice - \$18
- (5) Research time, when available (per hour)
 - (A) Staff research time - \$20
 - (B) Computer research time - \$100
- (6) Reproduction of Board meeting recordings, if available;
 - (A) Audio recording, each tape copy (per tape), \$15
 - (B) Video recording, each tape copy (per tape), \$15
- (7) Certification of open public record, not certification of grades, \$1.00 per page.
- (8) Certified letters of good standing or licensure verification, \$10

(c) Board Open records, which are available and may be obtained from the Board's ~~our~~ website www.pharmacy.ok.gov at - no charge.

535:1-11-5. Miscellaneous

Miscellaneous fees, as set by the Board, shall be as follows:

- (1) Oklahoma ~~State Board of Pharmacy~~ lawbook - \$10
- ~~(2) Duplicate certificate of registration - \$30~~
- ~~(2) (3)~~ Certification of grades - \$10 - (exempt if ELTP)
- ~~(3) (4)~~ Special inspection fee (each) Not to exceed - \$200
- ~~(5) Pharmacist Reinstatement: Back fees + CE + 15 hours CE penalty + \$100~~
- ~~(4) (6)~~ Fines – Not (not to exceed on each count) - \$3,000
- ~~(5) (7)~~ Duplicate for lost/destroyed license, renewal receipt, permit, or practical experience certificate - \$10.
- ~~(6) (8)~~ Late fee for renewal of registration, licenses and/or permits if not received by the Board office within 15 days after expiration date - \$ fee x 2
- ~~(7) (9)~~ Insufficient check charge - \$25
- ~~(8) (10)~~ Reinstatement of permits or licenses other than pharmacists - \$ fee x 2

SUBCHAPTER 13. REQUESTS FOR RULE CHANGES [REVOKED]

535:1-13-1. Requests for rule changes-[REVOKED]

~~(a) All interested persons may request the Board to promulgate, amend or repeal a rule.~~

~~Requests are to be made in writing and filed with the Director. Each request shall set forth fully the reasons for its submission; the alleged need or necessity therefor; whether or not the proposal conflicts with any~~

~~existing rule, and what, if any, statutory provisions are involved.~~

~~(b) Each request to the Board to promulgate, amend or repeal a rule, shall be considered by the Board at its next regular meeting or may be continued for further consideration to a subsequent meeting.~~

~~(c) After consideration of a request to promulgate, amend or repeal a rule the Board may:~~

~~(1) approve the proposed change, to be formally considered for adoption as required by the current Administrative Procedures Act; or,~~

~~(2) determine that the proposal or request is not a necessary rule, amendment or repeal; refuse the same and reflect the decision in the regular minutes of the Board.~~

SUBCHAPTER 15. DECLARATORY RULINGS

535:1-15-1. Definitions

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

"**Declaratory ruling**" means an interpretation of a Board's rule by the Board.

535:1-15-2. Declaratory rulings

(a) Any person affected by any of the rules or orders of the ~~Oklahoma State Board of Pharmacy~~ may request in writing an interpretation or ruling regarding the application of such rules or orders.

(b) Such request shall state fully the facts to which the rule or order may apply, and the particular rule or order about which the question exists.

(c) The request or inquiry will be added to the agenda for the next scheduled Board meeting but may, if necessary, be continued for further consideration to a subsequent meeting.

(d) The Board's interpretation of the rule or order will be furnished in writing to the person making the request within a reasonable time after Board consideration ~~thereafter~~.