ARKANSAS REGISTER



Proposed Rule Cover Sheet

Secretary of State John Thurston 500 Woodlane Street, Suite 026 Little Rock, Arkansas 72201-1094 (501) 682-5070 www.sos.arkansas.gov



Name of Department
Agency or Division Name
Other Subdivision or Department, If Applicable
Previous Agency Name, If Applicable
Contact Person
Contact E-mail
Contact Phone
Name of Rule
Newspaper Name
Date of Publishing
Final Date for Public Comment
Location and Time of Public Meeting

ARKANSAS STATE BOARD OF PHARMACY RULES

RULE 1—GENERAL OPERATIONS

01-00-0001—DESCRIPTION OF THE BOARD

The Arkansas State Board of Pharmacy shall consist of six pharmacist members as provided by Arkansas Code 17-92-201 (a)(1) and (2), AND 17-92-201(d) plus a consumer member and a senior citizen consumer member as provided by Arkansas Code 17-92-201 (a)(3). The qualifications, powers, and duties of the Board shall be those enumerated by the provisions of A.C.A. 17-92-201 through 17-92-208. (10/9/80, amended 6/20/91)

01-00-0002—LOCATION OF BOARD OFFICES

The office of the Arkansas State Board of Pharmacy shall be located at 322 South Main Street, Suite 600, Little Rock, Arkansas. All communications thereto may be addressed to Arkansas State Board of Pharmacy, 322 South Main Street, Suite 600, Little Rock, AR 72201. (10/9/89, Amended 5/31/2014)

01-00-0003—REQUESTS FOR INFORMATION

Any person or persons seeking information respecting the Arkansas State Board of Pharmacy or desiring to submit complaints or charges thereto or make request thereof shall do so by filing with the Board an instrument in writing, signed by the writer and containing a return address. Communications need not be typed but should be legible. (10/9/80)

01-00-0004—LICENSEES GOVERNED BY PHARMACY PRACTICE ACT

Except wherein items of practice and procedure are specifically set out in these regulations rules, the practice and procedure before the Arkansas State Board of Pharmacy shall be governed by the provisions of the Pharmacy Practice Act. (10/9/80)

01-00-0005—CERTIFICATES OF LICENSURE--EXPIRATION

- (a) All retail pharmacy permits, out-of-state pharmacy permits, specialty pharmacy permits, nursing home consultant pharmacist permits and pharmacist licenses shall expire on December 31 of the first odd-numbered year following the date of their issuance.
- (b) All preceptor permits shall expire on December 31 of the first odd-numbered year following the date of their issuance.
- (c)
 - (1) An intern license issued to a student intern shall expire six (6) months following graduation or when the intern is issued a pharmacist license, whichever occurs first.
 - (2) Intern licenses issued to foreign graduates shall expire on December 31 of the second calendar year following the date of issuance or when the intern is issued a pharmacist license, whichever occurs first.
- (d) Non-renewable provisional licenses and provisional registrations shall expire six months after the date of issuance or upon issuance of a pharmacist, intern or technician license, whichever comes first.
- (e) All pharmacy technician permits, hospital pharmacy permits, ambulatory care center pharmaceutical services permits, wholesale distributors of legend or controlled substance

permits, wholesale distributors of medical equipment, legend devices, and medical gases permits, institutional pharmaceutical services permits, List I chemical permits and charitable clinic permits shall expire on December 31 of the first even-numbered year following the date of the issuance of the permit, license, registration, or certificate.

- (f) Charitable clinic permits shall expire on December 31 of the first even-numbered year following the date of the issuance of the permit, license, registration, or certificate.
- (g) Every license, permit, registration, and certificate not renewed within ninety (90) days after expiration thereof shall be null and void.
 - (1) Every licensed pharmacist engaged in the active practice of pharmacy shall pay to the Board of Pharmacy a renewal fee as defined in <u>regulation rule</u> 01-00-0007. If the renewal fee for any pharmacist license is unpaid by the first day of February following the date of expiration, the holder thereof must pay a penalty as defined in <u>regulation rule</u> 01-00-0007 for each month thereafter, provided that if the renewal is unpaid by the first day of April following the date of expiration, such certificate shall be null and void and the holder must be reinstated as a licensed pharmacist by satisfying the State Board of Pharmacy that he or she is of the same moral character and temperate habits as was required at the time of the original registration, and satisfy the Board of Pharmacy that he or she is competent and qualified to compound and fill prescriptions, and must pay a reinstatement fee as defined in <u>regulation rule</u> 01-00-0007 for each delinquent year up to a maximum as defined in <u>regulation rule</u> 01-00-0007 plus the current year's renewal fee.
 - (2) Every registered pharmacy technician shall pay to the Board of Pharmacy a renewal fee as defined in <u>regulation rule</u> 01-00-0007. If the renewal fee for any pharmacy technician registration is unpaid by the first day of February following the date of expiration, the holder thereof must pay a penalty as defined in <u>regulation rule</u> 01-00-0007 for each month thereafter, provided that if the renewal is unpaid by the first day of April following the date of expiration, such registration shall be null and void. The pharmacy technician may be reinstated as a pharmacy technician upon payment of a reinstatement fee as defined in <u>regulation rule</u> 01-00-0007 plus the renewal fee.
 - (3) Every nursing home consultant shall pay to the Board of Pharmacy a renewal fee as defined in <u>regulation rule</u> 01-00-0007. If the renewal fee for the nursing home consultant is unpaid by the first day of February following the date of expiration, the holder thereof must pay a penalty as defined in <u>regulation rule</u> 01-00-0007 for each month thereafter, provided that if the renewal is unpaid by the first day of April following the date of expiration, such registration shall be null and void.
 - (4) Every preceptor shall pay to the Board of Pharmacy a renewal fee as defined in regulation rule 01-00-0007. If the renewal fee for the preceptor license is unpaid by the first day of July following the date of expiration, the holder thereof must pay a penalty as defined in regulation rule 01-00-0007 for each month thereafter, provided that if the renewal is unpaid by the first day of September following the date of expiration, such registration shall be null and void.
 - (5) Every licensed pharmacy, hospital, ambulatory care center, wholesale distributor, List I chemical or supplier of medical equipment, legend device or medical gas shall pay to the Board of Pharmacy a renewal fee as defined in <u>regulation rule</u> 01-00-0007. If the renewal fee for any pharmacy or business license is unpaid by the first day of February following the date of expiration, the holder thereof must pay a penalty as defined in <u>regulation rule</u> 01-

00-0007 for each month thereafter, provided that if the renewal is unpaid by the first day of April following the date of expiration, such license shall be null and void.

(10/09/80, Revised 10/14/81, Act of 1985, 6/20/91, 8/23/96, 11/13/2006, and 7/27/2011)

01-00-0006—BOARD OF PHARMACY MEETING REQUIREMENTS

The Arkansas State Board of Pharmacy shall meet the second Tuesday and Wednesday in February, the second Tuesday and Wednesday in June or at the time of the Annual Meeting of the Arkansas Pharmacists Association in June, and the second Tuesday and Wednesday in October of each year--unless changed and announced in advance by the Board of Pharmacy. Examination of candidates for licensure to practice pharmacy shall be on dates, and at times and places as determined by the Board of Pharmacy. (10/09/80 Revised 6/20/91, and 11/13/2006)

01-00-0007—FEES CHARGED BY THE BOARD OF PHARMACY

- (a) The fees charged by the Arkansas State Board of Pharmacy for the various examinations, permits, licenses, certificates, and books issued by the board shall be as follows:
 - (1) The fee for examination to become a licensed pharmacist upon examination shall be twenty-five dollars (\$25.00) plus the actual cost of the examination;
 - (2) The fee for a license as a licensed pharmacist from another state by reciprocity (license transfer) shall be two hundred dollars (\$200);
 - (3)
- (A) The fee for the initial issuance of a license as a licensed pharmacist shall be seventyfive dollars (\$75.00);
- (B) The fee for the renewal of a license as a licensed pharmacist shall be seventy-five dollars (\$75.00) per year;
- (4)
 - (A)
- (i) The fee for issuance of a permit for the first time to operate an in-state pharmacy shall be three hundred dollars (\$300);
- (ii) The fee for renewal of a permit to operate an in-state pharmacy shall be one hundred fifty dollars (\$150) per year;
- (iii) When there is a change of ownership of an in-state pharmacy, a new permit must be obtained, and the fee shall be one hundred fifty dollars (\$150);
- (B)
- (i) The fee for issuance of a permit for the first time to operate a specialty pharmacy shall be three hundred dollars (\$300);
- (ii) The fee for renewal of a permit to operate a specialty pharmacy shall be one hundred fifty (\$150) per year;
- (iii) When there is a change in ownership in a specialty pharmacy, a new permit must be obtained and the fee shall be one hundred fifty dollars (\$150);
- (C)
- (i) The fee for issuance of a permit for the first time to operate an out-of-state pharmacy shall be three hundred dollars (\$300);
- (ii) The fee for renewal of a permit to operate an out-of-state pharmacy shall be one hundred fifty dollars (\$150) per year;

- (iii) When there is a change in ownership in an out-of-state pharmacy or drug store, a new permit must be obtained, and the fee shall be one hundred fifty dollars (\$150);
- (5) The fee for a certificate as a licensed pharmacist shall be ten dollars (\$10.00);
- (6) The fee for certifying grades in connection with an application for reciprocity (license transfer) shall be ten dollars (\$10.00);
- (7)
- (A) The fee for issuance of a hospital pharmaceutical service permit shall be three hundred dollars (\$300), and the fee for the renewal of a hospital pharmaceutical service permit shall be one hundred fifty dollars (\$150) per year.
- (B) When there is a change of ownership of a hospital pharmacy, a new permit must be obtained and the fee shall be one hundred fifty dollars (\$150);
- (C)
- (i) The fee for issuance of an ambulatory care center pharmaceutical service permit shall be three hundred dollars (\$300), and the fee for the renewal of an ambulatory care center pharmaceutical service permit shall be one-hundred fifty dollars (\$150) per year.
- (ii) When there is a change in ownership of an ambulatory care center pharmacy, a new permit must be obtained and the fee shall be one hundred fifty dollars (\$150);

(8)

- (A) The fee for issuance of an institutional pharmaceutical services permit shall be thirty-five dollars (\$35.00);
- (B) The fee for the renewal of an institutional pharmaceutical services permit shall be thirty-five dollars (\$35.00) per year;

(9)

- (A) The fee for issuance of, and the reinstatement of a nursing home pharmacy consultant permit shall be thirty-five dollars (\$35.00);
- (B) The fee for the renewal of a nursing home consultant pharmacist permit shall be thirty-five dollars (\$35.00) per year;
- (10) The fee for intern registration shall be forty-five (\$45.00) dollars.
- (11) The fee for change of pharmacist in charge of any pharmacy, or other facility as described at §17-92-403 shall be thirty-five dollars (\$35.00);
- (12) The fee for reinstatement of a pharmacist license shall be seventy-five dollars (\$75.00) for each delinquent year up to a maximum of three hundred dollars (\$300);
- (13) The fee for the Arkansas State Board of Pharmacy law book shall be twenty-five dollars (\$25.00) except to interns on initial licensure, and applicants for reciprocity, on a one-time basis. A copy of each edition as revised shall be provided free to each pharmacy permit holder;
- (14) The fee for a change of location inspection shall be one hundred dollars (\$100);
- (15) The penalty for late payment of renewal of any permit, license, registration or certificate, unless specifically stated in this <u>regulation rule</u>, shall be twenty dollars (\$20.00) per month beginning the first day of the second month after expiration, provided that if the renewal is not paid by the first day of the fourth month after expiration, the license shall be null and void;
- (16)

- (A) The fee for issuance of a wholesale distributor of legend drugs and/or controlled substances permit shall be three-hundred dollars (\$300), and renewal shall be one-hundred fifty dollars (\$150) per year;
- (B) When there is a change in ownership of a wholesale distributor of legend drugs and/or controlled substances, a new permit must be obtained and the fee shall be one hundred fifty dollars (\$150);

(17)

- (A) The fee for the original issuance of a pharmacy technician's permit shall not exceed thirty-five (\$35.00);
- (B) The fee for the renewal of a pharmacy technician's permit shall not exceed thirty-five dollars (\$35.00) per year;
- (C) There shall be no fee for the original issuance and renewal of a restricted charitable clinic pharmacy technician's permit issued pursuant to Board <u>Regulation rule</u> 04-03-0004 (f).
- (18) The reinstatement fee for a pharmacy technician's permit shall not exceed forty dollars (\$40.00); and

(19)

- (A) The application fee for a license to sell, rent, offer to sell, or rent directly to patients in this state any home medical equipment, legend devices, or medical gases shall not exceed two-hundred fifty dollars (\$250);
- (B) The license renewal fee shall not exceed one hundred twenty-five dollars (\$125);
- (C) The change of ownership fee shall not exceed one hundred twenty-five dollars (\$125).
- (20) The fee for issuance of a temporary permit for a pharmacist on active duty in a branch of the armed forces shall not exceed twenty-five dollars (\$25.00) and shall be administered as defined in regulation rule 02-00-0004.
- (21) The fee for registration as a preceptor shall be twenty dollars (\$20.00) every two years.
- (22)
 - (A) The fee for a permit for wholesale distributors of List I chemicals shall not exceed three hundred dollars (\$300), and the renewal shall not exceed one hundred fifty dollars (\$150) per year.
 - (B) When there is a change of ownership of a wholesale distributor of List I chemicals, a new permit must be obtained and the fee shall not exceed one hundred fifty dollars (\$150).
- (b) All fees for examination for license shall be payable with the application and shall not be subject to refund. All other fees are only refundable if it is determined that there has been an overpayment.
- (c) Should any license, certificate, or registration not be renewed within ninety (90) days after expiration thereof, it may be reinstated by the board as authorized in this section upon payment of the renewal fee and reinstatement fee. However, the following are not subject to reinstatement if not renewed within ninety (90) days after expiration:
 - (1) pharmacy permits,
 - (2) out of state pharmacy permits,
 - (3) specialty pharmacy permits,
 - (4) hospital permits,

- (5) ambulatory care center pharmacy permits,
- (6) wholesale distributors of legend drugs and/or controlled substance permits, or both; and
- (7) suppliers of medical equipment, legend devices, and/or medical gas licenses,
- (8) institutional pharmacy permits
- (9) List I chemical permits
- (10) charitable clinic permits.

(d)

- (1) All retail pharmacy permits, out of state pharmacy permits, specialty pharmacy permits, and pharmacist licenses expiring in odd-numbered years shall be renewed every two (2) years.
- (2) All pharmacy technician permits, hospital pharmaceutical service permits, ambulatory care center pharmaceutical services permits, wholesale distributors of legend or controlled substance permits, wholesale distributors of medical equipment, legend devices, and medical gases permits, wholesale distributors of List I chemicals, institutional pharmaceutical services permits, nursing home consultant pharmacists permits, charitable clinic permits and any other permit, license, registration, or certificate issued by the board expiring in even-numbered years and not covered in subdivision (d) (1) of this section shall be renewed every two (2) years.
- (3) The fee for any biennial renewal term will be the amount of two (2) annual renewal fees for the applicable license, permit, registration, or certification as provided in subsection (a) of this section.
- (4) If the initial licensure, permit, certificate, or registration occurs in the first year of a biennial renewal term, the applicant shall pay the appropriate initial fee and the applicable annual fee for the license, permit, certificate, or registration for the second year in the renewal term, as provided in subsection (a) of this section.
- (5) If the initial licensure, permit, certificate, or registration occurs in the second year of the biennial renewal term, the applicant will only pay the original fee and will not be responsible for the renewal fee until the biennial renewal period for the license, permit, certificate, or registration. 8/23/96 (Revised 6/19/97 8/19/99, 6/2001, 11/13/2006, and 7/5/2007)

01-00-0008—DECLARATORY ORDER

- (a) Scope-When a regulation rule, statute or order enforced by the Board of Pharmacy or its application will injure or threatens to injure a person in his person, business, or property, that person may file a petition for a declaratory order as to the applicability of that regulation rule, statute or order pursuant to this regulation rule.
- (b) Petition-Contents-The petition for a declaratory order shall contain the following:
 - (1) The venue, a heading specifying the subject matter and name of the petitioner and the name of the pleading;
 - (2) The name, address, and telephone number of the petitioner and whether petitioner is licensed by the Board under A.C.A. §17-92-101 *et seq.*;
 - (3) The name, address, and telephone number of petitioner's attorney, if any;
 - A statement of the injury to result from the <u>regulation rule</u>, statute or order or the application thereof to the petitioner;
 - (5) The declaratory ruling that the petitioner seeks;
 - (6) The regulation rule, statute or order which is the subject of the petition;

- (7) The facts relevant to the order which petitioner seeks; said statement of facts shall be complete, specific and particularized to the issue presented;
- (8) Memorandum of law and legal authorities in support of the order the petitioner seeks;
- (9) The name, address and telephone number of each person known to the petitioner who may have a specific personal interest in the application of the <u>regulation rule</u>, statute or order or who may be adversely affected by the declaratory order sought by the petitioner;
- (10) The signature of petitioner or petitioner's attorney, if any; and
- (11) All documents pertinent to the petition shall be attached thereto.
- (c) Filing of the Petition.
 - (1) The original and three copies of each petition shall be in writing and shall be delivered in person or by mail to the Executive Director of the Board during regular business hours at the Board's offices. The Executive Director shall mark said petition as having been received by the Board and return a file-marked copy to petitioner.
 - (2) In order to determine whether to issue a declaratory order, the Board will consider any pertinent issues including, without limitation, the following:
 - (A) whether the petition substantially conforms to section (b) above or is not supported by a memorandum of law in support of the petition;
 - (B) whether the petition is frivolous;
 - (C) whether the matter is within the jurisdiction of the Board;
 - (D) whether there is a genuine controversy of material fact, the resolution of which is necessary before any declaratory order may issue;
 - (E) whether the order will terminate a controversy or remove uncertainties as to the applicability to petitioner of any <u>regulation rule</u>, statute or order by the Board;
 - (F) whether the petition involves any subject, question or issue which the subject of a formal or informal matter or investigation currently pending before the Board, a court or other agency of this state or the federal government;
 - (G) whether the petition seeks a ruling on a moot or hypothetical question, speculative facts or will result in an advisory ruling or opinion;
 - (H) whether the issue presented is of such complexity that the Board has had insufficient opportunity or resources to develop a fully matured opinion;
 - (I) whether a declaratory order would provide a broad interpretation of a <u>regulation rule</u>, statute or order applicable to an entire class of persons;
 - (J) whether the promulgation of a <u>regulation rule</u> or an adjudication would be more appropriate to resolve the question; and
 - (K) any other pertinent matter.
- (e) Parties
 - (1) Petitioner, persons identified in section b (9) and the Board shall be parties to a proceeding for a declaratory order.
 - (2) Any other person may seek leave of the Board to intervene in such proceeding and leave to intervene will be granted at the sole discretion of the Board.
 - (3) A petition to intervene shall be filed in the manner as set forth the same matters as required by section b herein. Any reference to "petitioner" herein also refers to any person who has been granted leave to intervene, unless the context clearly indicates to the contrary.
- (f) Disposition of Petition. The Board may:
 - (1) Decide the issue solely upon the facts presented in the petition; in such case the decision will apply only to the extent of the facts presented in the petition and amended to the petition;

- (2) Require that additional information be submitted before the petition will be considered; in such event the additional facts will be considered as an amendment to the petition;
- (3) Require the petitioner to provide notice of the pendency of the proceeding to persons who may be necessary parties as well as other persons;
- (4) Schedule a time, date and place at which the Board will conduct a hearing on the petition for the purpose of obtaining additional facts or inquiring into any facts set forth in the petition; notice of the hearing and purpose therefore shall be provided to the petitioner.
- (5) Schedule a date, time and place at which the petitioner and other persons may make an oral presentation on the petition;
- (6) Consider the petition and any attachments without oral presentation; and/or

(g) Order

- (1) The Board shall state its decision in writing signed by the President or other person designated by the Board.
- (2) The Board's decision deciding the issue presented by the petition shall include findings of fact and conclusions of law supporting the declaratory order; the decision may be in the form of a letter or pleading.
- (3) The Board's decision shall be rendered and entered as promptly as reasonably practicable considering the facts, circumstances, complexity and other factors pertinent to the proceeding.
- (4) The order shall be served upon the petitioner and any other parties to the proceeding by certified mail, return receipt requested. (Adopted 8/19/99)

01-00-0009—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 person or facility holding a permit, license, registration, certificate, or credential issued by the Arkansas State Board of Pharmacy that is found to be violating any Arkansas Code pertaining to the practice of pharmacy or any regulation rule of the Arkansas State Board of Pharmacy as well as any other applicable state or federal law, rule, or regulation.
- (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 to a warning notice may be referred by the Executive Director of the Board for review and hearing.
- (f) Board review of two warning notices. Any registrant receiving two or more warning notices within a twelve-month period may be referred to the Board for review and hearing. (Adopted 2/2001)

<u>01-01-0010 – LICENSURE FOR ACTIVE DUTY SERVICE MEMBERS, RETURNING</u> <u>MILITARY VETERANS, AND SPOUSES</u>

(a) The Arkansas State Board of Pharmacy shall allow the following individuals to secure employment with a temporary license, certificate, or permit while completing the application process for full licensure or registration if the individual is the holder in good standing of a substantially equivalent license, certificate, or permit issued by another state:

(1) An active duty uniformed service member stationed in the State of Arkansas;

(2) A returning military veteran applying for licensure within one (1) year of his or her discharge from active duty; or

(3) The spouse of a person under subdivisions (b)(1) and (b)(2) of this section. (b) The Arkansas State Board of Pharmacy shall expedite the process and procedures for full licensure or registration for the following individuals:

(1) An active duty uniformed service member stationed in the State of Arkansas; (2) A returning military veteran applying within one (1) year of his or her discharge from active duty; or

(3) The spouse of a person under subdivisions (c)(1) and (2) of this section.