Arkansas State Board of Pharmacy
322 South Main Street, Suite 600 Little Rock, AR 72201
P: 501.682.0190 F: 501.682.0195
asbp@arkansas.gov • www.pharmacyboard.arkansas.gov
John Clay Kirtley, Pharm.D., Executive Director

January 5, 2022

Arkansas Secretary of State
500 Woodlane St.
Little Rock, AR 72201

Re: Arkansas State Board of Pharmacy

RULE 9 - PHARMACEUTICAL CARE/PATIENT COUNSELING

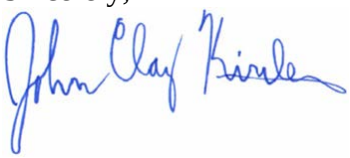
To Whom it May Concern,

The above listed rule will tentatively be discussed in a public hearing on Wednesday, February 9, 2022 at 1:00PM, at the Arkansas State Board of Pharmacy, 322 South Main St., Suite 600, Little Rock, AR 72201. I am including information for this regulation change to include:

- This Cover letter
- Arkansas Register Cover Sheet
- Summary of Substantive Changes for each proposed change
- Public Notice for hearing
- Mark-Up Copy of each Rule

If you have any additional questions regarding this matter then please do not hesitate to contact me.

Sincerely,



John Clay Kirtley, Pharm.D.
Executive Director

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 Arkansas Department of Health

Agency or Division Name ADH Division of Health Related Boards and Commissions – State Board of Pharmacy

Other Subdivision or Department, If Applicable

Previous Agency Name, If Applicable

Contact Person John Clay Kirtley

Contact E-mail john.kirtley@arkansas.gov

Contact Phone 501-682-0190

Name of Rule RULE 9 - PHARMACEUTICAL CARE/PATIENT COUNSELING

Newspaper Name Arkansas Democrat Gazette

Date of Publishing 1/7/2022, 1/8/2022, 1/9/2022

Final Date for Public Comment 2/9/2022 at end of public hearing

Location and Time of Public Meeting Wednesday, February 9, 2022 at 1:00PM, Arkansas State Board of Pharmacy, 322 South Main Street, Suite 600, Little Rock, AR 72201

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Proposed Rule

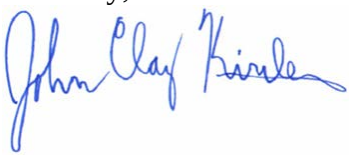
RULE 9 - PHARMACEUTICAL CARE/PATIENT COUNSELING

Summary of Proposed Changes

These changes will outline requirements of Act 503 of 2021 to describe how the Board of Pharmacy may establish and publish statewide written protocols as developed and adopted with consultation and approval of the Arkansas State Medical Board for the treatment of certain health conditions adopted by rule.

If you have any additional questions regarding this matter, please do not hesitate to contact me.

Sincerely,



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PUBLIC NOTICE

On Wednesday, February 9, 2022 at 1:00PM, the Arkansas State Board of Pharmacy will hold a public hearing in the Arkansas State Board of Pharmacy Offices, 322 South Main, Suite 600, Little Rock, AR 72201. The following rule changes will be considered:

RULE 7 - DRUG PRODUCTS/PRESCRIPTIONS

Proposed changes will update language regarding Therapeutic Substitution as outlined in Act 503 of 2021 and establish Prescription Delivery Standards as outlined in Act 922 of 2021.

RULE 9 - PHARMACEUTICAL CARE/PATIENT COUNSELING

Proposed changes will describe how the Board of Pharmacy may establish and publish statewide written protocols as developed and adopted with consultation and approval of the Arkansas State Medical Board for the treatment of certain health conditions adopted by rule as outlined in Act 503 of 2021.

Public comments will be accepted until the conclusion of the public hearing. A copy of the proposed rule changes and instructions to participate in the meeting can be obtained through our website at http://www.pharmacyboard.arkansas.gov/pharmacy-lawbook by calling (501) 682-0190, writing:

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201,
or by emailing the Board of Pharmacy at asbp@arkansas.gov

RULE 9 —PHARMACEUTICAL CARE/PATIENT COUNSELING

09-00: PATIENT COUNSELING

09-00-0001--PATIENT INFORMATION, DRUG USE EVALUATION, AND PATIENT COUNSELING

The intent of this regulation is to improve pharmaceutical care by defining basic standards of care. Pharmacy care/pharmaceutical care is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are: (1) cure of disease, (2) elimination or reduction of a patient's symptomatology, (3) arresting or slowing a disease process, or (4) preventing a disease or symptomatology.

Pharmaceutical care (clinical pharmacy) involves four major functions on behalf of the patient: (1) identifying potential and actual drug-related problems, (2) resolving actual drug related problems, (3) preventing potential drug-related problems, and (4) optimizing patient therapy outcomes. It is recognized that the patient might be best served if medication is not provided.

(a) Patient information (profile)
In order to effectively counsel patients, the pharmacist must, through communication with the patient or caregiver, make a reasonable effort to obtain, record, and maintain the following information for each patient. It is recognized that most of this can be obtained using pharmacy technicians and designed forms, etc.
(1) Name, address, telephone number;
(2) Date of birth (age);
(3) Gender;
(4) Medical history
(A) Significant patient health problems known to the pharmacist;
(B) Prescription drug reactions/prescription drug allergies;
(C) List of prescription medications and legend drug administration devices known to the pharmacist.
(5) Transitory patients or situations where the pharmacy will only provide medication one time
In obtaining patient information, if the pharmacist knows or is informed by the patient that this is a one-time situation, the pharmacist may forego the above requirement to record and maintain the information.
(6) Pharmacist comments

(b) Drug use evaluation for new and refill prescriptions
Drug use evaluation or drug utilization review includes the following activities:
(1) The pharmacist shall evaluate the prescription or medication order for:
(A) Reasonable dose and route of administration;
(B) Reasonable directions for use.
(2) The pharmacist shall evaluate medication orders and patient information for:
(A) Duplication of therapy - is the patient taking the same or similar medication(s)?;

(B) Prescription drug-prescription drug interactions;
(C) Proper utilization (over or underutilization);
(D) Known drug allergies.

(3) Drug-drug contraindications as defined by the Board. (Is this medication contraindicated with another medication the patient is taking?)
(4) It is recognized that the ultimate decision to use the medication or not use the medication rests with the physician who has more complete patient information. It is the pharmacist's responsibility to monitor the patient's medication therapy in the areas addressed in this regulation and inform the physician of the suspected problem.
(5) If a problem is suspected and the physician is informed, the pharmacist shall document the process.

(c) Patient counseling:
(1) A pharmacist shall counsel the patient or caregiver "face to face" if the patient or caregiver is in the pharmacy. If not, a pharmacist shall make a reasonable effort to counsel the patient or caregiver;
(2) Alternative forms of patient information may be used to supplement, but not replace face-to-face patient counseling;
(3) Patient counseling, as described herein, shall also be required for outpatients of hospitals and institutions when medications are dispensed on discharge from the hospital or institution.
(4) Patient counseling as described in this regulation shall not be required for inpatients of a hospital or institution where a nurse or other licensed health care professional is authorized to administer the medication. However, the pharmacist shall provide drug therapy counseling it is when professionally deemed to be appropriate and when medications are provided by the pharmacy, and when a pharmacist is on duty and a patient is discharged from the hospital or institution.
(5) The pharmacist shall maintain and make available to all patients appropriate patient-oriented reference materials USP-DI or *Facts and Comparisons Patient Drug Facts* or an equivalent or better publication as determined by the Board.
(6) It is recognized that the ultimate decision to not provide patient counseling rests with the physician. If the physician in specific instances (blanket requests not accepted) requests that information NOT be provided to the patient and gives reason, the pharmacist should honor that request in almost all instances.

(d) "Patient counseling" shall mean the effective communication by the pharmacist of information, as defined in this act to the patient or caregiver, in order to improve therapeutic outcome by encouraging proper use of prescription medications and drug delivery devices.
(1) For original prescription medication orders, (excluding renewed or updated prescriptions the patient has been recently taking) and orders for legend devices, specific areas of counseling shall include:
(A) Name and general description of the medication dispensed, i.e. antibiotic, antihistamine, blood pressure medicine, etc.
(B) Name, general description and directions for use of drug delivery devices, i.e., insulin syringes, morphine pump, etc.

(C) Explanation of route of administration, dosage, times of administration, and continuity of therapy;
(D) Special directions for storage as deemed necessary by the pharmacist;
(E) If the drug has been determined to have a significant side effect by the Board of Pharmacy, the patient shall be properly counseled to the extent deemed necessary by the pharmacist.
(F) When the prescription drug dispensed has a significant side effect, if taken with over-the-counter drugs, the pharmacist should counsel the patient about that interaction. (Example: coumadin with aspirin)
(G) If the prescription medication is significantly affected by food or diet, the pharmacist should so advise the patient. (Example: tetracycline with milk or food)
(H) The pharmacist shall inform the patient or caregiver that he/she is available to answer questions about medications or general health information.

(2) Refills--On refills the pharmacist shall present the opportunity for the patient or caregiver to ask questions. However, counseling on refills is not required except when needed in the professional judgment of the pharmacist.

(d) Drug interactions – significant side effects
Recognizing that a pharmacist cannot be expected to recognize all possible drug interactions and also recognizing that the pharmacist and the patient do not have time to explain the numerous side effects of drugs, the pharmacy shall maintain a computer program which will identify significant drug interactions. (These are drugs with side effects which may be managed most effectively if the patient is aware of the specific side effect and what to do if it occurs.) The pharmacist in charge will be responsible for assuring that the computer system adequately flags and warns the pharmacist of any occurrence of significant drug interactions or significant side effects. (If a pharmacy was in business before September 1, 1997, and at that time, did not have a computer system, said pharmacy may substitute *Patient Drug Facts* or other drug interaction manuals to reference drug interactions and side effects for effective patient counseling. This method should only be used until such time as the pharmacy acquires an adequate computer program as described in this section.)
The pharmacist will be responsible for counseling the patient on these interactions with verbal and, where appropriate, written information. (2/12/91, 2/10/98, 07/15/2004)

09-00-0002—PRESCRIPTION ORDERS TO ADMINISTER MEDICATION AND/OR IMMUNIZATIONS

Except as limited by these rules or Arkansas statutes §17-92-101, an Arkansas licensed pharmacist, intern or pharmacy technician has the ability to administer medications they have been trained to administer.
(Revised 07/15/2004, 03/14/2006, 7/5/2007, 7/27/2011 and 12/1/2017)

09-02-0000 POINT-OF-CARE TREATMENT

(a) A pharmacist who tests for conditions under § 17-92-101(17)(A)(x) shall:
(1) Hold a license to practice pharmacy in this state;
(2) Report a diagnosis or suspected existence of reportable diseases as required by the Arkansas Department of Health;

(3) Furnish patient records to a healthcare practitioner designated by the patient upon the request of the patient; and

(4) Maintain records of all patients receiving services under this section for two (2) years.

(b) A pharmacist may treat the following conditions within the framework of a statewide written protocol:

(1) Influenza;

(2) Pharyngitis caused by Streptococcus A;

(3) Sars Coronavirus or

(4) Other health conditions adopted by rule according to the pharmacy practice act.

(c) The Board of Pharmacy shall publish the statewide written protocol as developed and adopted with consultation and approval of the Arkansas State Medical Board. The statewide written protocol:

(1) shall include the age of people that can be treated under the protocol.

(2) shall include medicinal drugs approved by the United States Food and Drug Administration which are indicated for treatment of these conditions, including without limitation any over-the-counter medication.

(3) shall not include any controlled substances in Schedule I-IV.

(d) A pharmacist shall only treat conditions for which the pharmacist has tested and that are approved under subdivision (17)(A)(x)(c) or board rules as described in statute.

(e) This subsection does not apply to specific acts of drug therapy management or disease state management delegated to a pharmacist based upon a written protocol or patient care plan approved by a physician (17-92-101).