

ARKANSAS REGISTER

Transmittal Sheet

Use only for **FINAL** and **EMERGENCY RULES**



Secretary of State

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For Office

Use Only:

Effective Date _____ Code Number _____

Name of Agency ADH Division of Health Related Boards and Commissions

Department Board of Pharmacy

Contact John Clay Kirtley E-mail john.kirtley@arkansas.gov Phone 501-682-0190

Statutory Authority for Promulgating Rules 17-92-205(a)

Rule Title: RULE 9 - PHARMACEUTICAL CARE/PATIENT COUNSELING

Intended Effective Date

(Check One)

☐ Emergency (ACA 25-15-204)

☐ 10 Days After Filing (ACA 25-15-204)

☒ Other 5/10/2022
(Must be more than 10 days after filing date.)

Legal Notice Published

Final Date for Public Comment

Reviewed by Legislative Council

Adopted by State Agency

Date

1/7/2022

2/9/2022

4/21/2022

2/9/2022

Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218)

John Clay Kirtley

john.kirtley@arkansas.gov

4/26/2022

Contact Person

E-mail Address

Date

CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted
In Compliance with the Arkansas Administrative Act. (ACA 25-15-201 et. seq.)

Signature

501-682-0190

john.kirtley@arkansas.gov

Phone Number

E-mail Address

Director, Arkansas State Board of Pharmacy

Title

4/26/2022

Date



Arkansas State Board of Pharmacy

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John Clay Kirtley, Pharm.D., Executive Director



April 26, 2022

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

Re: Arkansas State Board of Pharmacy

RULE 7—DRUG PRODUCTS/PRESCRIPTIONS
RULE 9 - PHARMACEUTICAL CARE/PATIENT COUNSELING

To Whom it May Concern,

The above listed rules were reviewed last week by ALC and updated for the effective dates of 5/10/2022. I am attaching copies of both rules in their final form along with copies of the Arkansas Register Transmittal Sheet.

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

Sincerely,

A handwritten signature in blue ink that reads "John Clay Kirtley". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

John Clay Kirtley, Pharm.D.
Executive Director

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 rule 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 rule 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 rule 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 and 5/10/2022)

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.

(Amended 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).

(Adopted 5/10/2022)