ARKANSAS REGISTER

Transmittal Sheet

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For Office Use Only:

Effective Date _____ Code Number _____

Name of Agency Arkansas State Board of Pharmacy

Department _____

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

Rule Title: Regulation 9 - Pharmaceutical Care/Patient Counseling

Intended Effective Date (Check One)

- ☐ Emergency (ACA 25-15-204)
- ☐ 10 Days After Filing (ACA 25-15-204)
- ☑ Other 12/1/2017 (Must be more than 10 days after filing date.)

	Date
Legal Notice Published	8/26/2017
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Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218)

John Clay Kirtley, PharmD | john.kirtley@arkansas.gov | 11/17/2017

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

Executive Director, Arkansas State Board of Pharmacy

Title

November 17, 2017

Date

Revised 7/2015 to reflect new legislation passed in the 2015 Regular Session (Act 1258). This act changed the effective date from 30 days to 10 days after filing the rule.

REGULATION 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

(a) Except as limited by these rules, an Arkansas licensed pharmacist has the ability to administer medications.
(b) Authority to administer medications/immunizations:
(1) An Authority to Administer is a written protocol, as defined in ACA § 17-92-101, from a practitioner for administration by a pharmacist of an approved medication or immunization.
(2) Pharmacists may provide pharmaceutical care to patients seven (7) years of age and older by administering medications or immunizations to an eligible patient upon receiving an Authority to Administer or a valid prescription order by a practitioner so authorized to prescribe such medications or immunizations as provided in ACA § 17-92-101(16)(A)(i). After completing the course of study described in (b)(5)(B) – (E)

of this section, licensed interns, as defined by Regulation 02-01-0003 (a), may provide pharmaceutical care to patients seven (7) years of age and older by administering medications or immunizations to an eligible patient, under the supervision of an appropriately licensed pharmacist with an Authority to Administer and in accordance with Regulations 02-01-004 and 02-01-0005(h).

(2) An Authority to Administer, once granted, is valid for a time period not to exceed one (1) year--unless such an order is invalidated by the practitioner granting the authority.

(3) An Authority to Administer is valid only for the pharmacist meeting the requirements set forth by the Arkansas State Board of Pharmacy and is not transferable.

(4) Unless otherwise specifically authorized by the Board, a person must possess a Certification for the Authority to Administer Medications/Immunizations issued by the Board to be qualified to accept an Authority to Administer. Certification for the credential (Authority to Administer Medications/Immunizations) will be issued to pharmacists who:

(A) obtain and maintain a license to practice pharmacy issued by the Arkansas State Board of Pharmacy;

(B) successfully complete a Board approved course of study, examination, and certification consisting of a training program that includes the current guidelines and recommendations of the Centers of Disease Control and Prevention. The course of study should include, at a minimum:

(i) basic immunology, including the human immune response;

(ii) the mechanism of immunity, adverse effects, dose, and administration schedule of available vaccines and approved medication/immunization;

(iii) how to handle an emergency situation in the event one should arise as a result of the administration of the medication /immunization;

(iv) how to persuade patients to be immunized and options for record keeping for patients that do get immunized;

(v) how to administer subcutaneous, intradermal, and intramuscular injection; and

(vi) record keeping requirements for these medications as required by law or regulation.

(C) obtain supervised instructions on the physical administration of vaccines during such course of study and certification;

(D) obtain and maintain current certification in Cardiopulmonary Resuscitation (CPR) or Basic Cardiac Life Support (BCLS), these certification courses must contain a live component where proficiency is tested; and

(E) successful completion of the above described course of study may be accomplished by:

(i) successfully completing the Board-approved course of study in a College of Pharmacy curriculum; or

(ii) successfully completing an American Council of Pharmaceutical Education (ACPE) Certificate Program of not less than twelve (12) hours on the course of study described in paragraph (b)(5)(B) above.

(F) The College of Pharmacy or the provider of said course of study shall provide participants a certificate of completion. A copy of said certificate shall be mailed to the Board of Pharmacy offices and placed in the pharmacist's permanent file.

(5) Pharmacists who complete items (A) through (E) of section (5) above may apply to the Board for a Certification for the Authority to Administer Medications/Immunizations. The certificate is valid until the pharmacist's license expires. The certificate shall be displayed in the pharmacy at which the pharmacist is working, and may be renewed when the pharmacist renews his or her license biennially after demonstrating continuing competency for certification.

(6) Continuing competency for certification for Authority to Administer must be maintained. A minimum of two (2) of the thirty (30) hour requirement for continuing education, each biennium, must be dedicated to this area of practice. In addition, the pharmacist must maintain a current certificate in cardiopulmonary resuscitation (CPR) or basic cardiac life support (BCLS).

(7) An Authority to Administer order shall meet the following requirements:
(A) must properly identify the practitioner issuing the order;
(B) must identify the medication or vaccine covered in any such order;
(C) must identify the medication or vaccine administered, site of the administration, dose administered, identity of pharmacist administering the dose; and
(D) must bear the date of the original order.

(c) Record keeping: Pharmacists shall maintain the following information for a minimum of two years:

(1) Authority to Administer

(2) Signed Patient Consent Form containing at least the following information
(a) Name of Patient
(b) Description of the medication or vaccine
(c) Description of the risks and possible side effects of the medication or vaccine
(d) Lot number of the medication or vaccine
(e) Expiration date of the medication or vaccine
(f) Date of administration

(Revised 07/15/2004, 03/14/2006, 7/5/2007, 7/27/2011 and 12/1/2017)

09-01: DISEASE STATE MANAGEMENT

09-01-0001 DISEASE STATE MANAGEMENT

The purpose of this regulation is to provide standards for the maintenance of records of a pharmacist engaged in the provision of disease state management as authorized in §17-92-101 (16) and §17-92-205 (a).

(a) Definitions. The following words and terms, when used in this regulation, shall have the following meanings, unless the context clearly indicates otherwise:

(1) "Act" means the Arkansas Pharmacy Practice Act

(2) "Board" means the Arkansas State Board of Pharmacy

(3) "Confidential record" means any health-related record maintained by a pharmacy or pharmacist--such as a patient medication record, prescription drug order, or medication order.

(4) "Disease state management" means the performance of specific acts of disease state management delegated to a pharmacist for an individual patient by an authorized practitioner through written protocol. (Disease state management shall not include the

selection of drug products not prescribed by the practitioner, unless the drug product is named in the practitioner initiated protocol.)

(5) "Written protocol" means a practitioner's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Arkansas State Medical Board under the Medical Practice Act.

(A) A written protocol must contain at a minimum the following:

(i) A statement identifying the individual practitioner authorized to prescribe drugs and responsible for the delegation of disease state management;

(ii) A statement identifying the individual pharmacist authorized to dispense drugs and to engage in disease state management delegated by the practitioner;

(iii) A statement identifying the types of disease state management decisions that the pharmacist is authorized to make which shall include:

(a) A statement of the ailments or diseases involved, drugs, and types of drug therapy management authorized; and

(b) A specific statement of the procedures, decision criteria, or plan the pharmacist shall follow when exercising disease state management authority

(iv) A statement of the activities the pharmacist shall follow in the course of exercising disease state management authority, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation shall be recorded within a reasonable time of each intervention and may be performed on the patient medication record, patient medical chart, or in a separate log book; and

(v) A statement that describes appropriate mechanisms and time schedule for the pharmacist to report to the physician monitoring the pharmacist's exercise of delegated disease state management and the results of the disease state management.

(B) A standard protocol may be used, or the attending practitioner may develop a disease state management protocol for the individual patient. If a standard protocol is used, the practitioner shall record, what deviations if any, from the standard protocol are ordered for that patient;

(C) Maintenance of records:

(i) Every patient record required to be kept under this regulation shall be kept by the pharmacist and be available, for at least two (2) years from the date of such record, for inspecting and copying by the Board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.

(ii) Patient records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(a) The records maintained in the alternative system contain all of the information required on a manual record; and

(b) The data processing system is capable of producing a hard copy of the record upon the request of the Board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(D) Written protocol:
  (i) A copy of the written protocol and any patient-specific deviations from the protocol shall be maintained by the pharmacist and available for inspection by a Board Inspector upon request.
  (ii) Written protocols, including standard protocols, any patient specific deviations from a standard protocol, and any individual patient protocol, shall be reviewed by the practitioner and pharmacist at least annually and revised, if necessary. Such review shall be documented in the pharmacist's records. Documentation of all services provided to the patient, by the pharmacist, shall be reviewed by the physician on the schedule established in the protocol.
  (iii) Any protocol from a practitioner shall be maintained in the pharmacy and available for inspection by a Board Inspector upon request.

(E) Confidentiality:
  (i) A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential records. If confidential health information is not transmitted directly between a pharmacy and a practitioner, but is transmitted through a data communication device, the confidential health information may not be accessed or maintained by the operator of the data communication device unless specifically authorized to obtain the confidential information by this regulation.
  (ii) Confidential records are privileged and may be released only to:
    (a) the patient or the patient's agent;
    (b) practitioners and other pharmacists when, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being;
    (c) other persons, the Board, or other state or federal agencies authorized by law to receive such information;
    (d) a law enforcement agency engaged in investigation of suspected violations of the Controlled Substances Act; or
    (e) a person employed by any state agency which licenses a practitioner as defined in the Act if such person is engaged in the performance of the person's official duties.
  (iii) This regulation shall not affect or alter the provisions relating to the confidentiality of the physician-patient communication as specified in the Medical Practice Act.
  (Adopted 8/19/99)

09-01-0003 —QUALIFICATIONS, RESOURCES, AND RECORD KEEPING REQUIRED FOR PRACTICING DISEASE STATE MANAGEMENT IN ARKANSAS.

(a) To practice disease state management a pharmacist must:
  (1) be a licensed pharmacist in the State of Arkansas
  (2) complete requirements for a credential as established by a Board of Pharmacy approved organization.

(b) Resource requirements for the provision of disease state management services shall include—but are not limited to the following:

(1) Maintain a distinct area that provides privacy for the provision of disease state management services;
(2) Maintain references that include a current copy/edition of applicable national practice guidelines and such other resources as may be necessary for the provision of optimal care;
(3) Maintain devices, supplies, furniture, and equipment as may be needed for the provision of optimal care.

(c) Record keeping requirements for disease state management.
The pharmacist shall record, maintain, and transfer data essential to the continuity of care and consistent with all applicable state and federal laws and regulations; and these records and all related files shall be available to the Arkansas State Board of Pharmacy inspectors and professional staff upon request. Additionally, a transferable pharmaceutical care record is to be maintained and is to include:
(1) The written request for consultation from the patient or physician;
(2) The physician approved protocol and/or patient care plan, which is to recognize all concomitant diseases and the patient's complete medication history/profile;
(3) Pharmacy progress notes; and,
(4) Laboratory data.
(Adopted 8/19/99, Revised 11/12/2009)

09-01-0004 —MINIMUM COMPETENCIES AND STANDARDS

(a) Minimum competencies for pharmaceutical care in all disease state management areas:
(1) The pharmacist shall be capable of identifying and accessing the patient's current health status, health-related needs and problems, and desired therapeutic outcomes.
(2) The pharmacist shall be capable of implementing, and evaluating a pharmaceutical care plan that assures the appropriateness of the patient's medication(s), dosing regimens, dosage forms, routes of administration, and delivery systems.
(3) The pharmacist shall be capable of communicating appropriate information to the patient and/or caregiver and other health care professionals regarding prescription or non-prescription medications and/or medical devices, disease states, or medical conditions, and the maintenance of health and wellness.
(4) The pharmacist shall be capable of monitoring and documenting the patient's progress toward identified endpoints and outcomes of the pharmaceutical care plan and shall intervene when appropriate.
(Adopted 8/19/99, Revised 11/12/2009)

09-01-0005 —NOTIFICATION OF CREDENTIAL IN DISEASE STATE MANAGEMENT REQUIRED:

Every pharmacist who receives a credential in disease state management from a Board approved organization must provide a copy of the credential to the Board of Pharmacy office. The Board of Pharmacy will notify any party requesting notification that the pharmacist is so qualified.

(Adopted 8/19/99, Revised 8/2001, 07/2004, 11/12/2009)

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas State Board of Pharmacy

DIVISION

PERSON COMPLETING THIS STATEMENT John Clay Kirtley, PharmD

TELEPHONE 501-682-0190 **FAX** 501-682-0195 **EMAIL:** John.Kirtley@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE REGULATION 9—PHARMACEUTICAL CARE/PATIENT COUNSELING

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☐ No ☒

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes ☐ No ☒

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☐ No ☒

   If an agency is proposing a more costly rule, please state the following:

   (a) How the additional benefits of the more costly rule justify its additional cost;
   N/A

   (b) The reason for adoption of the more costly rule;
   N/A

   (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;
   N/A

   (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.
   N/A

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

   (a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	0	General Revenue	0
Federal Funds	0	Federal Funds	0
Cash Funds	0	Cash Funds	0
Special Revenue	0	Special Revenue	0
Other (Identify)	0	Other (Identify)	0

Total	0	Total	0

(b) What is the additional cost of the state rule?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	0	General Revenue	0
Federal Funds	0	Federal Funds	0
Cash Funds	0	Cash Funds	0
Special Revenue	0	Special Revenue	0
Other (Identify)	0	Other (Identify)	0
Total	0	Total	0

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year	**Next Fiscal Year**
$ 0	$ 0
0	

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year	**Next Fiscal Year**
$ 0	$ 0
0	

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes ☐ No ☒

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

(1) a statement of the rule's basis and purpose;

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

(3) a description of the factual evidence that:
   (a) justifies the agency's need for the proposed rule; and
   (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

(4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:

(a) the rule is achieving the statutory objectives;
(b) the benefits of the rule continue to justify its costs; and
(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.