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# 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~~ 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 ~~regulation~~ 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 ~~regulation~~ 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)

**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).

State of Arkansas *As Engrossed: H2/24/21 H3/4/21*
93rd General Assembly **A Bill**
Regular Session, 2021 HOUSE BILL 1246

*By: Representatives L. Johnson, Bragg, Eubanks*
By: Senators D. Wallace, Hester

## For An Act To Be Entitled

AN ACT TO ALLOW PHARMACISTS TO TREAT CERTAIN HEALTH *CONDITIONS; TO MODIFY PHYSICIAN DISPENSING; TO ALLOW DELEGATION OF PHYSICIAN DISPENSING; AND FOR OTHER PURPOSES.*

## Subtitle

*TO ALLOW PHARMACISTS TO TREAT CERTAIN HEALTH CONDITIONS; TO MODIFY PHYSICIAN DISPENSING; AND TO ALLOW DELEGATION OF PHYSICIAN DISPENSING.*

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. DO NOT CODIFY. Purpose.

It is the purpose of this act to authorize pharmacists in Arkansas to test and screen for health conditions that the Centers for Medicare and Medicaid Services has determined qualify for a waiver under the federal Clinical Laboratory Improvement Amendments of 1988, the federal regulations adopted, or any established screening procedures that can safely be performed by a pharmacist.

SECTION 2. Arkansas Code § 17-92-101(17)(A)(x), concerning the definition of "practice of pharmacy", is amended to read as follows:

(x)(a) Providing pharmacy care~~; and~~.

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

*(1) Influenza;*

*(2) Pharyngitis caused by streptococcus A; or*

*(3) Other health conditions that can be screened utilizing the waived test under the Clinical Laboratory Improvement Amendments of 1988, that may be adopted by rule of the Arkansas State Board of Pharmacy, in consultation with and upon approval of the Arkansas State Medical Board.*

(c) A pharmacist shall only treat conditions for which the pharmacist has tested and that are approved under this subdivision (17)(A)(x)(c).

*(d)(1) The Arkansas State Board of Pharmacy, with consultation and upon approval of the Arkansas State Medical Board, shall adopt by rule:*

*(A) A formulary of medicinal drugs that a pharmacist may prescribe for treatment of conditions listed in subdivision (17)(A)(x)(b) of this section; and*

*(B) A written statewide protocol for conditions listed in subdivision (17)(A)(x)(b) of this section, which shall including without limitation age of people that can be treated and medications to be used to treat people under this subdivision.*

(2) The formulary 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) The formulary shall not include any controlled substance in Schedule I-IV or 21 U.S.C. § 812, as existing on January 1, 2021.

(e) A pharmacist may write a prescription for *over-the-counter medications, supplies, and devices; and*

*SECTION 3. Arkansas Code § 17-92-101(18), concerning the definition of "prescription", is amended to read as follows:*

*(18)(A)(i) "Prescription" means an order for medicine or medicines usually written as a formula by a physician, optometrist, dentist, veterinarian, or other licensed medicinal practitioner.*

*(ii) A prescription ~~It~~ contains the names and quantities of the desired substance, with instructions to the pharmacist for its preparation and to the patient for the use of the medicine at a particular time and may authorize the pharmacist to substitute a therapeutically equivalent drug that is at ~~a~~ an equal or lower cost to the patient and communicate that authorization by any generally accepted means of communication of a prescription from a prescriber to a pharmacist.*

*(B)(i) A ~~substitution of a therapeutically equivalent drug shall occur only after the prescriber grants such authorization for each prescription.~~ pharmacist whose practice is located within this state may substitute one (1) medication for a therapeutically equivalent medication.*

*(ii) However, a pharmacist shall not substitute one (1) medication for a therapeutically equivalent medication if:*

*(a) A prescription is in writing and the prescriber indicates in his or her own handwriting by name or initial that no substitution is to be made;*

*(b) A prescription is not in writing and the prescriber expressly indicates that the prescription is to be dispensed as communicated; or*

*(c) The Arkansas State Board of Pharmacy has determined that a therapeutically equivalent medication should not be substituted and has notified all pharmacists of that determination.*

*(C)(i) Before dispensing, the pharmacist shall discuss verbally any suggested substitution with the patient and inform the patient that the patient has a right to refuse the substitution.*

*(ii) The discussion under subdivision (18)(C)(i) of this section shall include without limitation:*

*(a) Notification to the patient that the therapeutically equivalent drug does not contain the identical active ingredient present in the prescribed drug; and*

*(b) All differences in dosage and frequency between the prescribed drug and the therapeutically equivalent drug.*

*(D) The pharmacist shall send notice of the substitution to the prescriber in writing or by electronic communication within twenty-four (24) hours after the drug is dispensed to the patient.*

*(E) Subdivision (18)(B) of this section 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 under subdivision (17)(A)(ix) of this section;*

SECTION 4. Arkansas Code Title 17, Chapter 92, Subchapter 1, is amended to add an additional section to read as follows:

17-92-118. Point-of-care treatment.

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 influenza to the 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.

*SECTION 5. Arkansas Code § 17-95-102 is amended to read as follows:*

*17-95-102. Legend drugs.*

*(a) ~~A dispensing physician is~~ As used in this section, a "dispensing physician" means a physician licensed under the Arkansas Medical Practices Act, § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq., who purchases legend drugs to be dispensed to his or her patients for the patients' personal use and administration outside the physician's office.*

*(b) This section ~~shall~~ does not apply to physicians who only dispense drugs in injectable form unless they are controlled substances, in which case the section shall fully apply.*

*(c) The dispensing physician shall:*

*(1) Personally dispense legend drugs, and the dispensing of such drugs may ~~not~~ be delegated;*

*(2)(A) Keep records of all receipts and distributions of legend drugs.*

*(B) The records shall be subject to inspection by the proper enforcement authority and shall be readily accessible for inspection and maintained in a central registry; and*

*(3) Label legend drugs with the following information:*

*(A) Patient's name and address;*

*(B) Prescribing physician's address and narcotic registry number issued by the United States Drug Enforcement Administration or national provider identification number;*

*(C) Date of dispensing; and*

*(D) Directions and cautionary statements, if any, as required by law.*

*(d)(1) A physician licensed under the Arkansas Medical Practices Act, § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq., shall not dispense legend drugs without prior approval by the Arkansas State Medical Board after application to the ~~board~~ Arkansas State Medical Board and on the showing of need.*

*(2) Licensed physicians who were dispensing in the ordinary course of their practice before April 12, 2013, shall be exempt from the requirements of this subsection.*

*(3) The ~~board~~ Arkansas State Medical Board shall determine whether need exists for a physician to dispense a specific legend drug to the physician's patient for a patient's personal use and administration outside of the physician's office based on such information as is necessary for the ~~board~~ Arkansas State Medical Board to determine:*

*(A) The legend drug or drugs that the physician requests to dispense;*

*(B) The ability of a physician's patient to obtain the legend drug from other medical professionals;*

*(C) The availability of the legend drug to be prescribed by the physician;*

*(D) The hours at which the legend drug may be obtained from other medical professionals;*

*(E) The distance the physician's patient must travel to obtain the legend drug from other medical professionals;*

*(F) Whether the physician has been investigated by the ~~board~~ Arkansas State Medical Board concerning the improper prescribing or use of a legend drug;*

*(G) Whether the physician has a financial relationship with the manufacturer of a legend drug that would create the appearance of a conflict of interest;*

(H) Whether the physician dispensing a legend drug will foster cost containment through improved efficiency and productivity; and

(I) The procedures the physician has implemented to:

(i) Assure compliance with the requirements of subsection (c) of this section;

(ii) Monitor and guard against potential drug interactions;

(iii) Store and safeguard the legend drugs; and

(iv) Comply with the Prescription Drug Monitoring Program Act, § 20-7-601 et seq., concerning the reporting requirements to the Prescription Drug Monitoring Program.

(4) This section does not apply to a prescription for:

(i) A ~~prescription for a~~ topical medication~~,~~;

(ii) Naloxone~~,~~;

(iii) Nicotine ~~nicotine~~ replacement therapy products~~, or~~;

(iv) Contraceptives; ~~contraceptives is exempt from subdivision (d)(3) of this section~~

(v) Acute care medication; or

(vi) Initial treatment for maintenance medication.

(e)(1) The ~~board~~ Arkansas State Medical Board shall enforce the provisions of this section and is authorized and directed to adopt rules to carry out ~~its purpose~~ the purpose of this section.

(2) The Arkansas State Medical Board shall adopt rules for physician dispensing that, at minimum, meet the same requirements for dispensing and oversight established by the Arkansas State Board of Pharmacy.

(f) As used in this section:

(1)(A) "Acute care medication" means a legend drug that is not a controlled substance and is prescribed for no more than fourteen (14) days of therapy.

(B) "Acute care medication" includes the following oral medications:

(i) Medications to treat infections;

(ii) Anti-inflammatory medications;

(iii) Antinausea medications;

(iv) Antihistamines; and

*(v) Cough medications;*

*(2) "Initial treatment" means the first prescription written for a specific prescription medication intended to initiate therapy on the medication; and*

*(3) "Maintenance medication" means a legend drug that:*

*(A) Is not a controlled substance;*

*(B) Is prescribed for no more than thirty (30) days; and*

*(C) Is used to treat one (1) of the following medical conditions:*

*(i) Hypertension;*

*(ii) Diabetes mellitus; or*

*(iii) Hypercholesterolemia.*

*SECTION 6. DO NOT CODIFY. Effective date.*

*Sections 1 -4 take effect on and after January 1, 2022.*

*/s/Johnson*

**APPROVED: 4/1/21**