Stricken language would be deleted from and underlined language would be added to the law as it existed prior to this session of the General Assembly.

State of Arkansas *As Engrossed: S2/26/01*
83rd General Assembly A Bill **Act 801 of 2001**
Regular Session, 2001 SENATE BILL 339

By: Senator P. Malone

For An Act To Be Entitled

AN ACT TO AMEND VARIOUS SECTIONS OF THE PHARMACY ACT, ARKANSAS CODE 17-92-101 THROUGH 17-92-909; TO AUTHORIZE MEMBERS OF THE BOARD OF PHARMACY TO ISSUE TEMPORARY PRACTICE PERMITS TO PHARMACISTS LICENSED IN OTHER STATES; TO ALLOW ISSUANCE OF LICENSES IN DISEASE STATE MANAGEMENT BY AGENCIES APPROVED BY THE ARKANSAS STATE BOARD OF PHARMACY; TO PROVIDE PHARMACISTS WITH GREATER FLEXIBILITY REGARDING THE DISPENSING OF GENERIC DRUGS AND PRICE GUIDELINES FOR GENERIC DRUGS; AND FOR OTHER PURPOSES.

Subtitle

AN ACT TO AMEND VARIOUS SECTIONS OF THE PHARMACY ACT, ARKANSAS CODE 17-92-101 THROUGH 17-92-909.

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

SECTION 1. Arkansas Code 17-92-101 is amended to read as follows:

17-92-101. Definitions.

As used in this chapter, unless the context otherwise requires:

(1) "Board of Pharmacy" means the Arkansas State Board of Pharmacy;

(2) "Credentialing" means the issuance <u>of or approval</u> by the Arkansas State Board of Pharmacy of a credential<u>, issued to a pharmacist by an agency approved by the board,</u> certifying that the pharmacist has met the standards of competency established by the board for disease state management

or other pharmacy services necessitating a credential;

(3) "Dentist" means a practitioner of dentistry duly licensed under the laws of this or some other state;

(4)(A) "Disease state management" means a strategy which utilizes a team-oriented, multidisciplinary approach to improve health care outcomes and quality of care, and when possible, to control health care cost through management of targeted chronic disease states.

(B) Disease state management focuses on improving health care from prevention to diagnosis and treatment to on-going follow-up.

(C) Disease state management will involve, but not be limited to, patient education and self-care techniques and out-patient drug therapy management pursuant to a patient care plan;

(5) "Drug" shall include all medicines and preparations recognized in the United States Pharmacopoeia or the National Formulary for substances intended to be used for the care, mitigation, or prevention of disease of either man or other animal;

(6) "Generically equivalent" means a drug that is pharmaceutically equivalent and therapeutically equivalent to the drug prescribed;

~~(6)~~(7) "Licensed pharmacist" means a person holding a license under the provisions of this chapter;

~~(7)~~(8) "Medicine" means a drug or preparation of drugs in suitable form for use as a curative or remedial substance;

~~(8)~~(9) "Optometrist" means a practitioner of optometry duly licensed under the laws of this state;

~~(9)~~(10) "Patient care plan" means a written course of action which is patient or physician or pharmacist specific and disease specific for helping a patient to achieve outcomes that improve a patient's quality of life;

~~(10)~~(11) "Pharmacy" means the place licensed by the board in which drugs, chemicals, medicines, prescriptions, and poisons are compounded, dispensed, or sold at retail;

~~(11)~~(12) "Pharmacy care" means the process by which a pharmacist in consultation with the prescribing practitioner identifies, resolves, and prevents potential and actual drug-related problems and optimizes patient therapy outcomes through the responsible provision of drug therapy or disease

state management for the purpose of achieving any of the following definite outcomes that improve a patient's quality of life:

(A) Cure of disease;

(B) Elimination or reduction of a patient's symptomology;

(C) Arresting or slowing a disease process; or

(D) Preventing a disease or symptomology;

(13) "Pharmaceutically equivalent" means drug products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical compendial or other applicable standards of strength quality, and purity according to the United States Pharmacopoeia or another nationally recognized compendium;

~~(12)~~(14) "Physician" means a practitioner of medicine duly licensed under the laws of this or some other state;

~~(13)~~(15) "Poisons" means any drug, chemical, medicine, or preparation liable to be destructive to adult human life in quantities of sixty (60) grains or less;

~~(14)~~(16) (A) "Practice of pharmacy" means the learned profession of:

(i) Dispensing, selling, distributing, transferring possession of, vending, bartering, or in accordance with regulations adopted by the board, administering drugs, medicines, poisons, or chemicals which, under the laws of the United States or the State of Arkansas, may be sold or dispensed only on the prescription and order of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals. Except in accordance with regulations adopted by the board as recommended by the Medications Administration Advisory Committee, the administration of medications shall be limited to the following classifications of medications: immunizations, vaccines, allergy medications, vitamins, minerals, antihyperglycemics, and antinausea medications. The administration of medications shall not include the administration of medications to any person under the age of eighteen (18);

(ii) Placing, packing, pouring, or putting in a container for dispensing, sale, distribution, transfer possession of, vending, or bartering any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Arkansas, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs,

medicines, poisons, or chemicals;

(iii) Placing in or affixing upon any container described in subdivision (14)(A)(ii) of this section a label required to be placed upon drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals;

(iv) Preparing, typing, or writing labels to be placed in or affixed on any container described in subdivision (14)(A)(ii) of this section, which label is required to be placed upon drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals;

(v) Interpreting prescriptions for drugs, medicines, poisons, or chemicals issued by practitioners authorized by law to prescribe drugs, medicines, poisons, or chemicals which may be sold or dispensed only on prescription;

(vi) Selecting, taking from, and replacing upon shelves in the prescription department of a pharmacy or apothecary drugs, medicines, chemicals, or poisons which are required by the law of the United States or the State of Arkansas to be sold or dispensed only on prescription of a practitioner authorized by law to prescribe them;

(vii) Compounding, mixing, preparing, or combining drugs, medicines, chemicals, or poisons which, under the laws of the United States or the State of Arkansas, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe them;

(viii) Advising and providing information concerning utilization of drugs and devices and participation in drug utilization reviews;

(ix)(a) Performing a specific act of drug therapy management or disease state management delegated to a pharmacist for an individual patient based upon a written protocol or a patient care plan approved by the patient's physician, who shall be licensed in this state under the Arkansas Medical Practices Act, § 17-95-201 et seq.

(b) Drug therapy management shall not include the selection of drug products not prescribed by the physician, unless the drug products are either named in the physician-initiated protocol or the physician-approved patient care plan;

(x) Providing pharmacy care; and

(xi) Providing pharmacokenetic services.

(B) The provisions of subdivisions (14)(A) and (C) of this section shall not apply to employees of wholesale drug companies or other drug distributors who do not fill prescriptions or sell or dispense drugs to the consumer.

(C)(i) The board may permit pharmacy technicians other than pharmacists or interns to perform some or all of those functions described in board regulations under the direct, personal supervision of a licensed pharmacist pursuant to regulations defining the minimum qualifications of such employees, the ratio of pharmacy technicians to supervising pharmacists and the scope of the duties, practices, and procedures which the board determines will promote the delivery of competent, professional pharmaceutical services and promote the public health and welfare. Nothing in this chapter shall be construed as allowing pharmacy technicians to administer medications.

(ii) The conduct of a pharmacy technician is the responsibility of the pharmacist-in-charge and supervising pharmacist of the pharmacy who shall not permit the employee to perform any act, task, or function which involves the exercise of independent judgment by the employee.

(iii) Pharmacy products prepared by pharmacy technicians shall be verified for accuracy by the supervising pharmacist prior to release for patient use, and the verification shall be documented.

(iv) The use of pharmacy technicians in a manner not authorized by this chapter or regulations promulgated hereunder shall be unprofessional conduct by the pharmacist-in-charge and the supervising pharmacist.

(v) It is recognized that hospital pharmacy technicians as defined in § 17-92-602(5) are governed by the Hospital Pharmacies Act, § 17-92-601 et seq., and related board regulations developed pursuant to that subchapter;

~~(15)~~(17) "Prescription" means an order for medicine or medicines usually written as a formula by a physician, optometrist, dentist, veterinarian, or other licensed medicinal practitioner. 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;

~~(16)~~(18) "Proprietary medicines", when not otherwise limited, means remedies that a certain individual or individuals have the exclusive right to manufacture or sell;

~~(17)~~(19) "Supervision" means under the direct charge or direction and does not contemplate any continued absence of such supervision;

(20) "Therapeutically equivalent" means pharmaceutically equivalent drug products that, if administered in the same amounts, will provide the same therapeutic effect, identical in duration and intensity;

~~(18)~~(21) "Veterinarian" means a practitioner of veterinary medicine duly licensed under the laws of this or some other state; and

~~(19)~~(22) (A) "Written protocol" means a physician's order, standing medical order, standing delegation order, or other order or protocol as defined by regulation of the Arkansas State Medical Board under the Arkansas Medical Practices Act, § 17-95-201 et seq.

(B) Except for immunizations and vaccinations, which may be general protocols, protocols shall be patient or physician or pharmacist specific for prescriptions or orders given by the physician authorizing the protocol.

SECTION *2*. Arkansas Code 17-92-308, regarding reciprocity for pharmacists licensed in other states, is amended by adding the following additional subsection:

(c)(1) In the interim between sessions of the board and upon satisfactory evidence of the fitness, as established by board regulation, of an applicant for reciprocity, any member of the board, in his or her discretion, may issue a temporary certificate which shall authorize the holder to practice pharmacy as set forth in Section 17-92-101.

(2) The temporary certificate shall expire on the date of the next meeting of the board after the granting of the certificate, whether that meeting is a regular meeting or a called meeting at which reciprocity is considered.

SECTION *3*. Arkansas Code 17-92-316 is amended to read as follows:

17-92-316. Credential required for professional pharmacy service.

~~(a) The Arkansas State Board of Pharmacy shall issue a credential in disease state management, or any other pharmacy service that necessitates a~~

~~credential, as defined by board regulations, if the candidate meets the competencies, standards, and objectives defined by the board's regulations.~~

(a)(1) The Arkansas State Board of Pharmacy may provide by regulation for credentialing and approval of pharmacists to practice disease state management and any other pharmacy services determined by the board to require a credential.

(2)(A) The credentials may be issued by agencies approved by the board to pharmacists who qualify pursuant to minimum competencies, standards, objectives, and qualifications determined by the board.

(B) However, a credential shall not authorize the pharmacist to practice the credentialed pharmacy service in Arkansas until after the board has determined that the credentialed pharmacist meets the above minimum competencies, standards, objectives, and qualifications determined by the board.

~~(b) A pharmacist who holds any credential issued under subsection (a) of this section shall renew the credential annually.~~

(b) The board shall adopt regulations necessary and appropriate to implement the credentialing and the board’s approval of pharmacists to practice disease state management and other credentialed pharmacy services, including:

(1) Identification of areas of credentialed pharmacy services;

(2) Identification of the minimum competencies, standards, objectives, and qualifications necessary for a credential and the board’s approval to practice in each area of credentialed pharmacy service;

(3) Identification of the standards for qualifying an agency to issue credentials for areas of pharmacy services;

(4) The procedure and standards, which may include a practical examination, for the board’s review and approval of a credential and determination of a pharmacist’s qualifications to practice disease state management or other credentialed pharmacy service;

(5) The conversion of a credential previously issued by the board for the practice of disease state management or other pharmacy service to a credential issued by an approved credentialing agency;

(6) Continuing professional education and other measures to maintain pharmacists’ continuing competency in disease state management and other credentialed pharmacy services.

(c) The board shall promulgate regulations to:

(1) Identify areas of credentialing;

(2) Establish procedures for initial application and renewal;

(3) Define the minimum competencies and standards to be examined;

(4) Define the qualifications for credentialing; and

(5) Define required continuing education, competencies, standards, and other information necessary to implement this chapter.

SECTION *4*. Arkansas Code 17-92-503 is amended to read as follows:

17-92-503. Generic substitutions.

(a)(1) When a pharmacist receives a prescription for a brand or trade name drug product, the pharmacist may dispense, except as provided in subsection (b) of this section, a lower cost generically equivalent drug product ~~unless such drug product appears on the nonequivalent drug product list as provided in § 17-92-504~~.

(2) The total amount charged for the substituted generically equivalent drug product or for dispensing the drug product shall not exceed the amount normally and regularly charged under comparable circumstances by the pharmacist for that drug product or for the dispensing of that drug product.

(3) A pharmacist may not dispense a drug product with a total charge that exceeds the total charge of the drug product originally prescribed unless agreed to by the purchaser.

(b) The pharmacist shall not dispense a generically equivalent drug product under subsection (a) of this section if:

(1) The prescriber, in the case of a prescription in writing signed by the prescriber, indicates in his own handwriting by name or initial that no substitution shall be made;

(2) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated; ~~or~~

(3) The person for whom the drug product is prescribed indicates the prescription is to be dispensed as written or communicated~~.~~<u>; or</u>

<u>(4) The board has determined that the drug should not be substituted and has notified all pharmacists of that determination.</u>

SECTION *5*. Arkansas Code 17-92-503, regarding substitution of generic for brand-name drugs, is amended by adding the following additional subsection:

(c)(1) The Arkansas State Board of Pharmacy shall determine which drugs are generically equivalent as defined in this act, relying on standards scientifically supported and generally accepted in the field of pharmacy, and shall notify each licensed pharmacist and the Arkansas State Medical Board of this determination.

(2) In making this determination, the Arkansas State Board of Pharmacy may use a nationally recognized reference source that meets the requirements of this act, notifying each licensed pharmacist and the Arkansas State Medical Board of the reference source to be used and any additions or deletions the Board may make in its discretion.

SECTION *6*. Arkansas Code 17-92-504 is repealed:

~~17-92-504. Nonequivalent drug product list.~~

~~(a)(1) The Arkansas State Board of Pharmacy shall be responsible for determining and designating drug products which in its best judgment are not equivalent in quality and effectiveness and which, because of nonequivalency, would pose a substantial threat to the health, safety, and welfare of the people of Arkansas if such drug products were subject to dispensing under the provisions of § 17-92-503.~~

~~(2) The Arkansas State Board of Pharmacy shall promulgate a nonequivalent drug product list of those drug products which it has determined are not equivalent in quality and effectiveness.~~

~~(3) The Arkansas State Board of Pharmacy shall provide a copy of the nonequivalent drug product list and changes to each pharmacist licensed with the Arkansas State Board of Pharmacy and to the Arkansas State Medical Board.~~

~~(b)(1) From time to time the Arkansas State Board of Pharmacy shall make such additions to or deletions from the nonequivalent drug product list as it deems appropriate and in the best interest and for the health, safety, and welfare of the people of this state.~~

~~(2) Notification of additions or deletions promptly shall be made to each pharmacist licensed with the Arkansas State Board of Pharmacy and to the Arkansas Medical Board.~~

~~(c) No pharmacist may dispense a generically equivalent drug product as provided in § 17-92-503 if the drug product appears on the current nonequivalent drug product list as promulgated by the Arkansas State Board of Pharmacy in accordance with subsection (d) of this section.~~

~~(d)(1) In determining and designating drug products which are not equivalent in quality and effectiveness, including the promulgation of the nonequivalent drug product list and additions and deletions thereto, the Arkansas State Board of Pharmacy shall comply with the provisions of the Arkansas Administrative Procedure Act, as amended, § 25-15-201 et seq.~~

~~(2) However, any opponent to the inclusion within, addition to, or deletion from the nonequivalent drug product list of any drug product shall have the burden of proof to show cause why the inclusion, addition, or deletion should not be made.~~

/s/ P. Malone

APPROVED: 3/15/2001