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ARKANSAS REGISTER

Transmittal Sheet

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

Secretary of State
Mark Martin
State Capitol, Suite 026
Little Rock, Arkansas 72201-1094
(501) 682-3527
www.sos.arkansas.gov

For Office Use Only:

Effective Date _____ Code Number _____

Name of Agency Arkansas State Board of Pharmacy

Department _____

Contact John Kirtley-Executive Director E-mail john.kirtley@arkansas.gov Phone (501)-682-0192

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

Rule Title: Regulation 3 - Pharmacy Technicians

Intended Effective Date (Check One)

- ☐ Emergency (ACA 25-15-204)
- ☐ 30 Days After Filing (ACA 25-15-204)
- ☒ Other 7/22/15 pend Leg Approval (Must be more than 30 days after filing date.)

Date	
Legal Notice Published	May 10, 2015
Final Date for Public Comment	Jun 9, 2015
Reviewed by Legislatice Council	Pending
Adopted by State Agency	6/9/2015

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

John Kirtley | john.kirtley@arkansas.gov | 6/15/2015

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
Title

Jun 15, 2015
Date

Revised 7/2011 to reflect new legislation passed in 2011.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas State Board of Pharmacy
DIVISION
PERSON COMPLETING THIS STATEMENT John Clay Kirtley, PharmD, Executive Director
TELEPHONE NO. 501-682-0190` **FAX NO.** 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 3 - Pharmacy Technicians

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 Does this proposed, amended, or repealed rule have a financial impact?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;

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

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

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

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

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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

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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.

REGULATION 3 —PHARMACY TECHNICIANS

03-00—PHARMACY TECHNICIANS—REGISTRATION/PERMIT REQUIRED

03-00-0001—DEFINITIONS

(a) "Pharmacy technician" means those individuals, exclusive of pharmacy interns, who assist the pharmacist in pharmaceutical services.

(b) "Supervision" means that the responsible pharmacist must be physically present to observe, direct, and supervise the pharmacy technician at all times when the pharmacy technician performs acts specified in this regulation. The supervising pharmacist is totally and absolutely responsible for the actions of the pharmacy technician. (Revised 11/15/2003)

03-00-0002—REGISTRATION REQUIRED

(a) A pharmacy technician shall register with the Board of Pharmacy on a form provided by the Board and undergo a criminal background check pursuant to Board Regulation 11;

(b) The registration shall expire on December 31 biennially as provided in Board Regulation 01-00-0007

(c) The registration fee for a pharmacy technician shall be defined in regulation 01-00-0007.

(d) No person shall work as a pharmacy technician prior to the Board issuing a certificate of registration and a permit. The permit shall be prominently displayed for public perusal in any pharmacy where the technician is working. The pharmacist-in-charge shall determine that the person is registered as a pharmacy technician and that the Board has issued a permit for the technician before the technician performs any tasks identified in regulation 03-00-0005 or 03-00-0006.

(e) If there is a change of mailing address for the pharmacy technician, the pharmacy technician shall immediately notify the Board of Pharmacy, in writing, of the new address.

(f) When a pharmacy technician leaves the employment of a pharmacy, the pharmacist in charge shall notify the Board, in writing, within fourteen (14) days.

(g) Any concurrent or subsequent employment at any pharmacy shall be reported to the Board of Pharmacy by both the pharmacy technician and the pharmacist in charge of the pharmacy where the pharmacy technician will be working. The pharmacist in charge must notify the Board of Pharmacy, in writing, of the exact date when the pharmacy technician will begin working. The pharmacy technician shall not work at that location until the Board of Pharmacy has received said notification.

(h) A pharmacy technician shall identify himself/herself as such in any telephone conversation regarding the functions of a pharmacy technician while on duty in the pharmacy.

(i) If the pharmacy technician is suspected to have, or evidence exists that a pharmacy technician may have violated any law or regulation regarding the practice of pharmacy, legend drugs or controlled substances, the pharmacist in charge shall notify the Board, in writing, within ten days or immediately if any danger to the public health or safety may exist. Any other pharmacist, whether or not practicing in the same pharmacy, who has such knowledge or suspicion, shall notify the Board in a like manner.

(j)

(1) The Board may, after notice and hearing, suspend or revoke the permit of a pharmacy technician upon a finding of the following:

(A) Violation of this regulation.

(B) Violation of any law or regulation regarding the practice of pharmacy.
(C) Violation of any law or regulation related to legend drugs or controlled substances.

(2) The Board shall follow the same procedures for hearings for pharmacy technicians as applicable to hearings for pharmacists as set forth in §17-92-101 et seq. and Board regulations. (Revised 11/15/2003 and 7/22/2015)

03-00-0003—A PHARMACY TECHNICIAN SHALL

(a) Conduct himself/herself professionally in conformity with all applicable federal, state, and municipal laws and regulations in his relationship with the public, health care professions, and pharmacists.
(b) Hold to the strictest confidences all knowledge concerning patrons, their prescriptions, and other confidence entrusted or acquired by him/her; divulging in the interest of the patron, only by proper release forms, or where required for proper compliance with legal authority.
(c) Provide valid and sufficient checks in payment for licenses or renewals.

03-00-0004—QUALIFICATIONS

(a) A high school graduate or a recognized graduate equivalency degree (G.E.D.).
(b) Of good moral character and temperate habits.
(c) The applicant must complete a criminal background check pursuant to Board regulation 11. If the pharmacy technician has a past record of alcohol or drug addiction or past record of violation of any law related to controlled substances, registration must be prior approved by the Board of Pharmacy. (Revised 11/15/2003)

03-00-0005—TASKS, RESPONSIBILITIES, AND DUTIES OF THE PHARMACY TECHNICIAN

(a) A pharmacy technician may assist the pharmacist in performing the following specific tasks in accordance with specific written policy and procedures established by the pharmacist-in-charge covering the areas described in this section. The supervising pharmacist is responsible for all tasks performed by the pharmacy technician. All tasks performed by the pharmacy technician must be supervised, checked, and approved by the supervising pharmacist. If the pharmacy technician performs any other task that is defined as the practice of pharmacy, it will be considered a violation.
(b) Approved tasks:
(1) Placing, packing, pouring, or putting in a container for dispensing, sale, distribution, transfer possession of, vending, or barter 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. This shall also include the adding of water for reconstitution of oral antibiotic liquids.
(2) Placing in or affixing upon any container described in this regulation, 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.
(3) 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.

(4)

(A) In a manual system -- preparing, typing, or writing labels to be placed or affixed on any container described in §17-92-101 on which a 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.

(B) In a computer system -- a pharmacy technician may enter information into the pharmacy computer. The pharmacy technician shall not make any judgment decisions that could affect patient care. The final verification of prescription-information, entered into the computer shall be made by the supervising pharmacist– prior to dispensing – who is then totally responsible for all aspects of the data and data entry.

(5) A pharmacy technician may obtain prescriber authorization for prescription refills provided that nothing about the prescription is changed; a pharmacy technician shall not receive prescriber authorization for a new prescription by telephone or by other verbal communication.

(6) Prepackaging and labeling of multi-dose and unit-dose packages of medication. The pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must check the finished task.

(7) Dose-picking for unit dose cart fill for a hospital or for a nursing home patient.

(8) Nursing unit checks in a hospital or nursing home. Pharmacy technicians may check nursing units for proper medication storage and other related floor stock medication issues. Any related medication storage problems or concerns shall be documented and initialed by a pharmacist.

(9) Patient and medication records. The recording of patient or medication information in manual or electronic system for later validation by the pharmacist may be performed by pharmacy technicians.

(10) The pharmacy technician shall not make any judgment decisions that could affect patient care.

(c)

(1) A pharmacy technician may assist in the following tasks when the pharmacist-in-charge has established a specific written policy and procedure for reconstitution of prefabricated non-injectable medication, bulk compounding, and/or preparation of parenteral products that establishes the order of addition of ingredients, the point at which the ingredients will be checked by the pharmacist, and the point at which the final product will be checked for integrity, correctness, and pharmaceutical elegance.

(2)

(A) Prior to any of these tasks being carried out by a pharmacy technician:

(i) the technician shall successfully complete an initial training, assessment of skills program, and test pursuant to a written training and assessment procedure established by the pharmacist-in-charge as provided in Regulation 03-00-0006; and

(ii) the pharmacist supervising a technician who engages in the above-referenced reconstitution, bulk compounding, and/or preparation of parental product shall

perform all calculations of ingredients and provide written directions for measurement of ingredients by the technician;

(B) Prior to dispensing any of said products for administration, the supervising pharmacist shall verify and approve in written form all ingredients as well as the final product.

(d)

(1) Bulk reconstitution of prefabricated non-injectable medication may include addition of multiple additives.

(2) Bulk compounding may include such items as sterile bulk solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of the facility.

(3) Preparation of parenteral products.

(A) Pharmacy technicians may:

(i) reconstitute and withdraw any amount (i.e. partial or entire amount) of an injectable medication to be administered to a patient; and

(ii) reconstitute, withdraw, and add any amount (i.e. partial or entire amount) of one or more injectable products to an IV solution to be administered to a patient. (Revised 10/12/99, 11/152003)

03-00-0006—DUTIES OF THE PHARMACIST IN THE USE OF PHARMACY TECHNICIANS

(a) A pharmacist-in-charge who utilizes a pharmacy technician to enter information into the pharmacy computer must develop and keep on file at the pharmacy, written policies and procedures which describe the process by which the supervising pharmacist verifies the accuracy, validity, and appropriateness of the filled prescription or medication order.

(b)

(1) A pharmacist-in-charge who utilizes a pharmacy technician for (1) bulk reconstitution of prefabricated non-injectable medication, (2) bulk compounding, and/or (3) preparation of parental products shall develop written policies and procedures for training, testing, and competency assessment of any pharmacy technicians performing these tasks.

(2) These policies and procedures shall incorporate those standards developed in the American Society of Health-Systems Pharmacists (ASHP) Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products (Copyright 2002) or a Board approved equivalent.

(c) The pharmacist-in-charge shall include, in the policy and procedure manual, the specific scope of responsibilities for pharmacy technicians or procedures delegated to pharmacy technicians.

(d) In each instance in which a pharmacy technician prepares or processes any medication identified in Regulation 03-00-0005, the supervising pharmacist

(1) Shall supervise the technician participating in those tasks as provided in Regulation 03-00-0001 (b);

(2) Shall personally determine all medication dose calculations and drug compatibilities, maintain proper storage conditions, and verify the proper labeling of all finished products, to include:

(A) For bulk products, the product name, name and strength of each drug, the name and volume of each vehicle, the preparation and expiration dates, and lot or equivalent numbers; and

(B) For individual products, the information required by law for individual prescriptions;

(3) Determine all medication dose calculations, drug compatibilities, maintain proper storage conditions, and verify the proper labeling of all finished products including appropriate expiration dates; and

(4) Shall record in written form his or her verification of the amount of each ingredient by volume, weight, or measure and of the final product by lot or equivalent number.

(e) The supervising pharmacist shall ensure that the pharmacy technician maintains confidentiality of all patient records.

(f) The pharmacist-in-charge shall maintain records of each drug product resulting from the procedures identified in paragraph (b) above for a period of two years and make said records available for inspection by the Board to include:

(1) A copy of all individual training, testing, and competency assessments;

(2) The record of verification of ingredients and final drug product described in paragraph (d) (4) above; and

(3) Policies and procedures applicable to producing said drug products.

(Revised 11/15/2003)

03-00-0007—PHARMACIST TO PHARMACY TECHNICIAN RATIO

(a) Retail or Specialty Pharmacy Settings

(1) Each pharmacist on duty in a retail or specialty pharmacy may utilize three pharmacy technicians to assist the pharmacist.

(2) In addition to the technician(s) described in this section, a pharmacist shall not also supervise more than one student intern unless the student(s) are working as part of an experiential learning experience as assigned by an ACPE accredited, Board approved College of Pharmacy. A graduate intern will not affect the ratio.

(b) Hospital or Ambulatory Care Facility Settings

(1) Pharmacy technicians used in assisting the pharmacist in pharmaceutical services for inpatients of the hospital, or patients of an ambulatory care facility shall be permitted to perform under direct supervision of a licensed pharmacist within the following conditions:

(A) The number of pharmacy technicians utilized in a hospital pharmacy or ambulatory care facility shall not exceed a ratio of three pharmacy technicians to each pharmacist on duty.

(B) This ratio shall not include pharmacy interns counted as either supportive personnel or pharmacists. Also excluded from the count of supportive personnel are those persons whose functions are not related to the preparation or distribution of medication. Such persons include clerks, secretaries, messengers, and delivery personnel. (8/23/96, Revised 10/2000, 8/2001 and 7/22/2015).