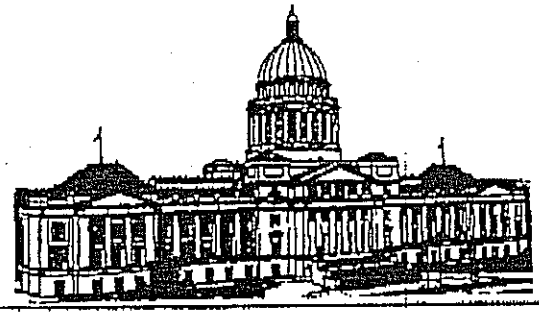
ARKANSAS REGISTER

Transmittal Sheet



Sharon Priest
Secretary of State
State Capitol Room 017
Little Rock, AR 72201-1094

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Name of Agency ARKANSAS STATE BOARD OF PHARMACY

Department

Contact Person John T. Douglas, P.D., or Sheila Castin

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

Intended Effective Date

- ☐ Emergency
- ☒ ~~30~~ 10 Days After Filing
- ☐ Other

	Date
Legal Notice Published . .	07/24,07/31,08/01,08/14
Final Date for Public Comment	08/20/97
Filed With Legislative Council	08/01/97
Reviewed by Legislative Council	09/04/97
Adopted by State Agency	08/20/97

CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted In Compliance with Act 434 of 1967 As Amended.

John T. Douglas PD
Signature

Executive Director
Title

September 5, 1997
Date

FILED
97 SEP -5 PM 4:44
SHARON PRIEST
SECRETARY OF STATE
STATE OF ARKANSAS
BY

REGULATION 63

DRUG THERAPY MANAGEMENT BY A PHARMACIST UNDER
WRITTEN PROTOCOL OF A PHYSICIAN

The purpose of this regulation is to provide standards for the maintenance of records of a pharmacist engaged in the provision of drug therapy management as authorized in §17-92-101 (14) 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 -- The Arkansas Pharmacy Practice Act
(2) BOARD -- The Arkansas State Board of Pharmacy
(3) CONFIDENTIAL RECORD -- any health-related record maintained by a pharmacy or pharmacist--such as a patient medication record, prescription drug order, or medication order.
(4) DRUG THERAPY MANAGEMENT --The performance of specific acts of drug therapy management delegated to a pharmacist for an individual patient by an authorized practitioner through written protocol. (Drug therapy 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 -- 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 drug therapy management;
(ii) a statement identifying the individual pharmacist authorized to dispense drugs and to engage in drug therapy management delegated by the practitioner;
(iii) a statement identifying the types of drug therapy management decisions that the pharmacist is authorized to make which shall include:
(I) A statement of the ailments or diseases involved, drugs, and types of drug therapy management authorized; and
(II) A specific statement of the procedures, decision criteria, or plan the pharmacist shall follow when exercising drug therapy management authority;

(iv) A statement of the activities the pharmacist shall follow in the course of exercising drug therapy 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 drug therapy management and the results of the drug therapy management.

(B) A standard protocol may be used, or the attending practitioner may develop a drug therapy 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:
  (1) Every patient record required to be kept under this regulation shall be kept by the pharmacist and be available, for at least two 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.
  (2) 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:
  (1) 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.
  (2) 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.
  (3) Any protocol from a practitioner shall be maintained in the pharmacy and available for inspection by a Board Inspector upon request.

(E) Confidentiality:
  (1) 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.
  (2) 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
    (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.
  (3) 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.

DEPARTMENT Arkansas State Board of Pharmacy
DIVISION
PERSON COMPLETING THIS STATEMENT John T. Douglas, P.D.
TELEPHONE NO. 682-0190 FAX NO. 682-0195

FINANCIAL IMPACT STATEMENT

To comply with Act 884 of 1995, please complete the following Financial Impact Statement and file with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Regulation 63

1. Does this proposed, amended, or repealed rule or regulation have a financial impact? Yes _____ No x

2. If you believe that the development of a financial impact statement is so speculative as to be cost prohibited, please explain. There is no way to measure the impact.

3. If the purpose of this rule or regulation is to implement a federal rule or regulation, please give the incremental cost for implementing the regulation.

1997-98 Fiscal Year		1998-99 Fiscal Year	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other		Other	
Total		Total	

4. What is the total estimated cost by fiscal year to any party subject to the proposed, amended, or repealed rule or regulation?

1997-98 Fiscal Year	1998-99 Fiscal Year
none	none

5. What is the total estimated cost by fiscal year to the agency to implement this regulation?

1997-98 Fiscal Year	1998-99 Fiscal Year
none	none

July 28, 1995

FILED
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SECRETARY OF STATE
STATE OF ARKANSAS
BY