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W. "BILL" McCUEN
SECRETARY OF STATE
LITTLE ROCK, ARKANSAS

Transmittal Sheet

W.J. "Bill" McCuen
Secretary of State
State Capitol
Little Rock, Arkansas 72201-1094

For Office Use Only: Effective Date 8/26/92 Code Number 007.07.92--002

Name of Agency Arkansas Department of Health

Department Division of Pharmacy Services and Drug Control

Contact Person Don Phillips Telephone 661-2325

Statutory Authority for Promulgating Rules Ark.Stat.Ann. Sections 5-64-506,5-64-702, 20-64-219,20-64-317

Intended Effective Date		Date
☐ Emergency	Legal Notice Published	6/21/92 thru6/27/92
☑ 20 Days After Filing	Final Date for Public Comment	7/20/92
☐ Other	Filed With Legislative Council	4/27/92
	Reviewed by Legislative Council	8/6/92
	Adopted by State Agency	7/23/92

CERTIFICATION OF AUTHORIZED OFFICER

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

Don Nutter
SIGNATURE

Director Div. Pharmacy Services & Drug Control
TITLE

8/6/92
DATE

007.07.92--002-

SEVERABILITY

If any provision of these Rules and Regulations or Amendments or the application thereof to any person or circumstances is held invalid, such invalidity shall not affect other provisions or applications of the Rules and Regulations or Amendments which can be given effect without the invalid provision or application and to this end the provisions of these Rules and Regulations and Amendments are declared to be severable.

REPEAL

All Regulations and parts of Regulations in conflict herewith are hereby repealed.

CERTIFICATION

This will certify the foregoing Amendents to the Rules and Regulations Pertaining to Controlled Substances were adopted by the Arkansas State Board of Health at a regular session of the Board was held in Little Rock, Arkansas on the 23rd Day of July, 1992 and after a Public Hearing on the 20th Day of July, 1992 held in Little Rock, Arkansas at the State Health Building.

Secretary
Arkansas Board of Health

The foregoing Amendents having been filed in my office are hereby adopted on this 31st Day of July, 1992.

Bill Clinton
Governor

ID:34

007.07.92-002

RULES AND REGULATIONS PERTAINING TO CONTROLLED DRUGS

Section I Authority

The following Rules and Regulations have been hereby promulgated pursuant to Arkansas Statutes Annotated § 5-64-508 (d) (e), § 5-64-702, § 20-64-219, § 20-64-317.

Section II Purpose

The problems of Drug Abuse in this State are increasing at an alarming rate and additional provisions are needed to assist in the enforcement of the provisions of Act No. 344 of 1937, Act No. 590 of 1971, and Act 492 of 1967 as amended, particularly the terms should be consistent with. Federal and other State Laws and Rules. The provision should be liberally constituted so as to effect the purposes of the Act.

Section III General Requirements

(Add copy of Proposed Rules and Regulations of the Arkansas State Board of Health pertaining to Controlled Drugs.)

Section IV Repeal

All Rules and Regulations and parts thereof in conflict herewith including but not limited to those adopted September 1, 1989 as amended are hereby repealed.

August 1992 Rev.

ID:34

ARKANSAS STATE BOARD OF HEALTH
RULES AND REGULATIONS
PERTAINING TO CONTROLLED DRUGS
(AUGUST 1992 REVISION)

SECTION 1. REGISTRATION

Every Practitioner as defined as follows shall obtain a registration from the Federal Drug Enforcement Administration, Department of Justice, unless exempted by Law.

(1) A physician, dentist, veterinarian, scientific investigator, pharmacist, researcher or other persons licensed, registered, or other wise permitted to dispense, distribute, administer or conduct research with respect to controlled substances in the course of professional practice or research in Arkansas:

(2) A pharmacy, hospital, or related institution, manufacturer, wholesaler, distributor or other institutions or facilities, licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in Arkansas.

(3) Persons authorized and registered by the Director, Arkansas Department of Health to engage in research on the use and effects of controlled substance, including persons conducting instructional activities, conducting chemical analysis or conducting animal training or animal euthanasia with controlled substances in the course of practice approved and registered by the Director.

A separate registration is required for each principle place of business or professional practice at one general physical location where controlled substances are maintained, manufactured, distributed, or dispensed.

SECTION 2. EXEMPT PREPARATIONS

A. A Controlled Substance listed in Schedule V which is not a prescription Drug as determined under the Arkansas Controlled Substances Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail provided, THAT:

(a) such dispensing is made only by a pharmacist;

(b) not more than 240cc (8 ounces) of any such Controlled Substance containing Opium nor more than 120cc (4 ounces) of any other such Controlled Substance nor more than 48 dosage units of any Controlled Substance containing Opium, nor more than 24 dosage units of any other such Controlled Substance may be dispensed at retail to the same purchaser in any given 48-hour period;

(c) the purchaser is at least 18 years of age.

(d) the pharmacist requires every purchaser of a Controlled Substance under this Section not known to him to furnish suitable identification (including proof of age where appropriate); and

(e) a bound record book for dispensing of Controlled Substances under this Section is maintained by the Pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of Controlled Substances purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the Substance to the purchaser.

SECTION 3. SECURITY REQUIREMENTS

A. All Practitioners shall provide effective controls and procedures to guard against theft and diversion of Controlled Substances.

Controlled Substances listed in Schedules I, II, III, IV and V shall be stored in a securely locked, substantially constructed cabinet.

However, pharmacies may disperse such Substances throughout the stock of Non- Controlled Substances in such a manner as to obstruct the theft or diversion of the Controlled Substances.

SECTION 4. PROCEDURE IN CASE OF LOSS

Each Practitioner and long term care facility shall notify the Division of Pharmacy Services and Drug Control, Arkansas Department of Health (661-2325) immediately upon discovery of any suspected loss, theft and/or diversion of any controlled substance.

SECTION 5. CLASSIFICATION OF CONTROLLED SUBSTANCES

Pursuant to of Ark. Stat. Ann. § 5-64-201 et. seq. the Commissioner of Narcotic Substances (the Director of the Arkansas Department of Health) may add Substances to or delete or reschedule all Substances enumerated in the Schedules, pursuant to the procedures of the Administrative Procedure Act as amended § 25-15-201 et. seq. with prior approval by the Arkansas Legislative Council.

The Controlled Substances listed in the Schedules shall be included by whatever official, common, usual chemical or trade name designated and shall be revised and republished annually. Pursuant to § 5-64-216.

SECTION 6. RECORDS OF CONTROLLED SUBSTANCES

Every Practitioner and long term care facility shall keep a record of such Drugs received and a record of all such Drugs administered, dispensed, or professionally used otherwise than by prescription.

The record shall in every case show the date of receipt, the name and address of the person or business from whom received, and the kind and quantity of Drugs received.

The record shall show the Drugs sold, administered, dispensed or otherwise disposed of; the date of selling, administering or dispensing; the name and address of the person to whom or for whose use the Drugs were sold, administered or dispensed or the owner and species of animal for which the Drugs were sold, administered or dispensed; and the kind and quantity of Drugs. Persons engaged in research on the use of controlled substances may withhold the names and other identifying characteristics of individuals who are the subjects of the research.

Institutional practitioner and Long Term Care Facility records must be designed so that all clinical personnel are using the same records in caring for patients and if diversion does occur the chance of discovery are increased. The basic records of receipt and disposition of controlled drugs within the institution are the patients medical records and the controlled drug procurement and disposition records.

Patient medication records shall consist of at least (1) physicians orders authorizing the dispensing and administration of medications, (2) medication administration record indicating the date, time and signature of nurse administering controlled drugs to the patient and (3) the nurses notes indicating the date, time and condition of the patient before and after the PRN controlled drug was administered and signature of the nurse administering the drug.

In addition to patients medical records, a record of the procurement and disposition for controlled drug must be maintained.

The disposition record must reflect the actual dosage administered to the patient, the patients name, date, time and signature of the nurse

~~administering the controlled drug. Any error of entry on the disposition~~ and procurement record shall follow a policy for correction of errors and accurate accountability. If the person who procures the controlled drug is not the person who administers the drug, then both persons must sign the disposition record.

When breakage or wastage of a controlled drug occurs, the amount administered and the amount wasted must be recorded by the nurse who wasted the drug and verified by the signature of a licensed person who witnessed the wastage and how it was wasted.

Adequate accountability does not require the use of a specific system or form, however the system employed must be designed so that all requirements listed above are met.

Each practitioner shall maintain inventory records in one consolidated record system. Records of Schedule I and II substance shall be maintained separately from all other records. Inventories of Schedule III, IV, V shall be maintained either separately from all other records or in such form that the information required is readily retrievable from the ordinary business records.

Every record shall be kept by the Registrant and be readily retrievable and available for at least two (2) years from the date of recordings, for inspection and copying by authorized agents of The Division of Pharmacy Services and Drug Control, Arkansas Department of Health.

Inventories and records of Narcotic Drugs listed in Schedules I, II, III, IV, and V shall be maintained either separately from all other

records or in such form that the information required is readily retrievable from ordinary business records or patients' records.

SECTION 7. SURRENDER OF UNWANTED CONTROLLED SUBSTANCES

All Controlled Substances no longer usable because of deterioration or expired dating or are unwanted, must be delivered in person or by registered mail or other means of shipment with return receipt to: Division of Pharmacy Services and Drug Control, Arkansas Department of Health, 4815 West Markham Street, Little Rock, AR 72205-3867 accompanied by all completed copies of Report of Drugs Surrendered (Form PhA:DC-1) furnished by the Health Department; or may be destroyed only by authorized Agents of The Arkansas State Board of Pharmacy or the Arkansas Department of Health on site.

Each drug item submitted for destruction by hospitals or related facilities must be identified in such a manner to determine the exact location in the facility where it was last recorded in accountability record to determine what person or persons had access or administered such drugs during the time it was in inventory of the facility.

SECTION 8. CONTROLLED DRUG PRESCRIPTIONS

A. Issue of Prescriptions

A prescription for Controlled Drugs may be issued only by an individual practitioner who is legally licensed in the State of Arkansas to practice his profession and who holds a current Federal D.E.A. Registration.

B. Purpose of Issue

~~(a) A prescription, in order to be effective in legalizing the~~ possession of Controlled Drugs and eliminating the need for use of order forms, must be issued for legitimate medical purposes. The responsibility for the proper prescribing and dispensing of Controlled Drugs is upon the practitioner, but a corresponding liability rests with the pharmacist who fills the prescription.

(b) An order purporting to be a prescription issued to an addict or habitual user of Controlled Drugs, not in the course of professional treatment but for the purpose of providing the user with Controlled Drugs sufficient to keep him comfortable by maintaining his customary use, is not a prescription within the meaning and interest of Ark. Stat. Ann. § 20-64-206, and the person knowingly filling such an order, as well as the person knowingly issuing it, shall be subject to the penalties provided by Ark. Stat. Ann. § 20-64-220.

(c) All prescriptions for Controlled Drugs and preparations not specifically exempt under Ark. Stat. Ann. § 20-64-208 and not subject to the oral prescriptions procedure shall be dated as of and signed on the day when issued and shall be dated as of and shall bear all the information required by Section 6, Uniform Narcotic Act, Ark. Stat. Ann. § 20-64-206 § 82-1006. Prescriptions (other than oral) shall be written in ink or indelible pencil or typewriter and shall be legibly signed by the practitioner. The duty of properly preparing or telephoning prescriptions, as the case may be, is upon the practitioner. A prescription required to be in writing may be prepared by a secretary or

agent for the signature of a practitioner, but the practitioner is responsible in case the prescription does not conform in all essential respects to the Law and Regulations. A practitioner shall sign a prescription in the same manner as he would sign a check or legal document. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form required by Ark. Stat. Ann. § 20-64-206.

C. Refilling

The refilling of a prescription for a Controlled Substance listed in Schedule II is prohibited. No prescription for a Controlled Substance listed in Schedule III or IV shall be filled or refilled more than six (6) months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five (5) times.

D. Partial Filling of Prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist may contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminal ill patient. The pharmacist must record on the prescription whether the patient is "terminal ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminal ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Prior to any subsequent partial filling the pharmacist is to determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial filling must not exceed the total quantity prescribed. Schedule II prescription for patients in a LTCF or patient with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

~~(c) Information pertaining to current Schedule II prescriptions for~~ patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit:

(1) Output (display or print) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription and the information required in Section 8-B(c).

(2) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.

(3) Retrieval of partial filled Schedule II prescription information is the same as required by Section 8-B(c) for Schedule III and IV prescription refill information.

(d) The authority to dispense Schedule II prescriptions for partial quantities does not apply to other classes of patients. Such as patient with severe intractable pain who are not diagnosed as terminal.

E. Telephoned or Oral Prescriptions

(a) In the case of an emergency situation, as defined by these Regulations, a pharmacist may dispense a Controlled Substance listed in Schedule II upon receiving oral authorization of a prescribing individual

~~practitioner provided that the quantity prescribed and dispensed is~~ limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner.)

For the purposes of authorizing an oral prescription of a Controlled Substance listed in Schedule II of the Arkansas Controlled Substance List, the term "emergency situation" means those situations in which the prescribing practitioner determines that:

(1) immediate administration of the Controlled Substance is necessary for proper treatment of the intended ultimate user;

(2) no appropriate alternative treatment is available (which includes the administration of a Drug which is not a Schedule II Drug; and

(3) it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the pharmacist dispensing the Drug prior to the dispensing.

The prescription shall be immediately reduced to writing by the pharmacist. Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing.

(b) A pharmacist may dispense a Controlled Substance listed in Schedule III or IV pursuant to an oral prescription made by an individual practitioner or communicated to a pharmacist by an employee or agent of

~~the individual practitioner, and promptly reduced to writing by the~~ pharmacist. The prescription must contain all the information required in the case of a written prescription except for the written signature of the individual practitioner.

F. Prescription transfers:

(a) The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis subject to the following requirements:

(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information.

(i) Write the word "VOID" on the face of the invalidated prescription.

(ii) Record on the reverse side of the invalidated prescription the name, address and D.E.A. registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescribing information.

(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(1) Write the word "TRANSFER" on the face of the transferred prescription.

(2) Provide all information required to be on a prescription pursuant to federal law (21 CFR 1306.05) and include:

(i) date of issuance of original prescription

(ii) original number of refills authorized on original prescription.

(iii) date of original dispensing

(iv) number of valid refills remaining and date of last refill

(v) Pharmacy's name, address, D.E.A. registration number and original prescription number from which the prescription information was transferred.

(vi) name of transfer pharmacist.

(3) Both the original and transferred prescription must be maintained for a period of two years from the date of last refill.

(c) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transfer.

SECTION 9. SCHEDULE II PRESCRIPTION

Prescriptions written for Schedule II Controlled Substances may be dispensed up to six (6) months from the date written if the dispenser is certain of the validity of the prescription. Prescriptions may be dispensed after six (6) months from the date written by verifying the validity from the prescriber and place the date and name of the dispenser of the verification on the front of the prescription.

SECTION 10. VIOLATIONS

Any violation found of these regulations of any practitioner as defined in Section I, may be reported by the Division of Pharmacy Services and Drug Control to the appropriate Licensing Board of the violator for possible disciplinary action by the Licensing Board.

SECTION 11. SUSPENSION, REVOCATION

The registration issued by the Department of Health to conduct procedures with controlled substances may be suspended or revoked for the following reasons:

1. The registrant has violated any provisions of these regulations.
2. The registrant has furnished false or fraudulent material information in application for registration.
3. The registrant has been convicted of a felony under any state or federal law relating to controlled substances.
4. The registrant has had his/her federal registration to handle controlled substances suspended or revoked.
5. The registrant has failed to renew his/her registration within 60 days after registration expires.

Proceedings pursuant to such suspension or revocation shall be governed by the rules of procedure of the State Department of Health.

SECTION 12 LABELING

Controlled drugs dispensed by a practitioner to a patient must contain a label bearing the date of dispensing; the name, address and telephone number of the dispenser; the serial number of the prescription; the name of the patient; the name of the prescribing practitioner, the name, strength and quantity of the medication dispensed, and directions for use including any required cautionary statements.

This section shall not apply to the dispensing of medication to inpatients in hospitals, or manufacturers samples in original containers issued by the prescribing practitioner.

In an appropriate manner, the prescribing practitioner may indicate that the name, strength and quantity of the drug dispensed shall be deleted from the label.