EXHIBIT D

DEPARTMENT OF HEALTH, STATE BOARD OF HEALTH

SUBJECT: Rules for Controlled Substances

DESCRIPTION: Summary of Proposed Amendments to Rules Pertaining to Controlled Substances for the State of Arkansas:

1.Section VI, (C), (4), Page 8, language is updated removing unwitnessed partial doses of controlled substances sent to Pharmacy Services and Drug Control. This language is removed to prevent confusion for DEA registered facilities regarding Title 21 Code of Federal Regulations Part 1317 related to disposal of controlled substances by registrants.

2.Section VII, (B), Page 9, pursuant to Code of Federal Regulations Part 1317, language is updated removing "hospitals" as entities required to surrender unwanted controlled substances to Pharmacy Services and Drug Control. Hospitals are DEA registrants and are required to comply with disposal processes outlined in Title 21 Code of Federal Regulations Part 1317.

3.Pursuant to Act 315 of 2019, language is updated removing the word "regulation" from the rule as applicable.

PUBLIC COMMENT: No public hearing was held on this rule. The public comment period expired on January 14, 2025. The agency indicated that it received no public comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The agency indicated that this rule has no financial impact.

LEGAL AUTHORIZATION: The Department of Health may promulgate rules necessary for the administration of Title 5, Chapter 64 of the Arkansas Code, regarding controlled substances. Ark. Code Ann. § 5-64-702.

QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT Arkansas Department of Health
BOARD/COMMISSION Division for Health Protection, Pharmacy Services Section
BOARD/COMMISSION DIRECTOR Shane David, PharmD, Branch Chief
CONTACT PERSON Laura Shue, General Counsel
ADDRESS 4815 West Markham Street, Slot 31, Little Rock, AR 72205
PHONE NO. (501) 661-2297 **EMAIL** Laura.Shue@arkansas.gov
NAME OF PRESENTER(S) AT SUBCOMMITTEE MEETING
Laura Shue; Shane David
PRESENTER EMAIL(S) Laura.Shue@arkansas.gov; Shane.David@arkansas.gov

INSTRUCTIONS

In order to file a proposed rule for legislative review and approval, please submit this Legislative Questionnaire and Financial Impact Statement, and attach (1) a summary of the rule, describing what the rule does, the rule changes being proposed, and the reason for those changes; (2) both a markup and clean copy of the rule; and (3) all documents required by the Questionnaire.

If the rule is being filed for permanent promulgation, please email these items to the attention of Rebecca Miller-Rice, miller-ricer@blr.arkansas.gov, for submission to the Administrative Rules Subcommittee.

If the rule is being filed for emergency promulgation, please email these items to the attention of Director Marty Garrity, garritym@blr.arkansas.gov, for submission to the Executive Subcommittee.

Please answer each question completely using layman terms.

****

1. What is the official title of this rule?
Rules for Controlled Substances

2. What is the subject of the proposed rule? Updated language to comply with changes by the Drug Enforceme

3. Is this rule being filed under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☑

If yes, please attach the statement required by Ark. Code Ann. § 25-15-204(c)(1).

If yes, will this emergency rule be promulgated under the permanent provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☐

4. Is this rule being filed for permanent promulgation? Yes ☑ No ☐

If yes, was this rule previously reviewed and approved under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☑

If yes, what was the effective date of the emergency rule? _____

On what date does the emergency rule expire?_____

5. Is this rule required to comply with a *federal* statute, rule, or regulation? Yes ☐ No ☑

If yes, please provide the federal statute, rule, and/or regulation citation.

6. Is this rule required to comply with a *state* statute or rule? Yes ☑ No ☐

If yes, please provide the state statute and/or rule citation.

Ark. Code §5-64-702; §20-64-219; §20-64-317

7. Are two (2) rules being repealed in accord with Executive Order 23-02? Yes ☐ No ☑

If yes, please list the rules being repealed.
If no, please explain.

Updated language to comply with changes by the Drug Enforcement Administration regarding partial doses and disposal of abandoned controlled substances.

8. Is this a new rule? Yes ☐ No ☑

Does this repeal an existing rule? Yes ☐ No ☑
If yes, the proposed repeal should be designated by strikethrough. If it is being replaced with a new rule, please attach both the proposed rule to be repealed and the replacement rule.

Is this an amendment to an existing rule? Yes ☑ No ☐
If yes, all changes should be indicated by strikethrough and underline. In addition, please be sure to label the markup copy clearly as the markup.

9. What is the state law that grants the agency its rulemaking authority for the proposed rule, outside of the Arkansas Administrative Procedure Act? Please provide the specific Arkansas Code citation(s), including subsection(s).

Ark. Code §5-64-702; §20-64-219; §20-64-317

10. Is the proposed rule the result of any recent legislation by the Arkansas General Assembly?
Yes ☐ No ☑

If yes, please provide the year of the act(s) and act number(s).

11. What is the reason for this proposed rule? Why is it necessary?

Updated language to comply with changes by the Drug Enforcement Administration regarding partial doses and disposal of abandoned controlled substances.

12. Please provide the web address by which the proposed rule can be accessed by the public as provided in Ark. Code Ann. § 25-19-108(b)(1).

https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules

13. Will a public hearing be held on this proposed rule? Yes ☐ No ☑

If yes, please complete the following:

Date: _____

Time: _____

Place: _____

Please be sure to advise Bureau Staff if this information changes for any reason.

14. On what date does the public comment period expire for the permanent promulgation of the rule? Please provide the specific date. _____

15. What is the proposed effective date for this rule? 5/1/2024

16. Please attach (1) a copy of the notice required under Ark. Code Ann. § 25-15-204(a)(1) and (2) proof of the publication of that notice.

17. Please attach proof of filing the rule with the Secretary of State, as required by Ark. Code Ann. § 25-15-204(e)(1)(A).

18. Please give the names of persons, groups, or organizations that you anticipate will comment on these rules. Please also provide their position (for or against), if known.

19. Is the rule expected to be controversial? Yes ☐ No ☑

If yes, please explain.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEPARTMENT Arkansas Department of Health
BOARD/COMMISSION Division for Health Protection, Pharmacy Services Section
PERSON COMPLETING THIS STATEMENT Laura Shue, General Counsel
TELEPHONE NO. (501) 661-2297 **EMAIL** Laura.Shue@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the Financial Impact Statement and email it with the questionnaire, summary, markup and clean copy of the rule, and other documents. Please attach additional pages, if necessary.

TITLE OF THIS RULE Rules for Controlled Substances

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 no, please explain:

   (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 reason for adoption of the more costly rule is based on the interests of public health, safety, or welfare, and if so, how; and

   (d) whether the reason for adoption of the more costly rule is within the scope of the agency's statutory authority, and if so, how.

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? n/a

Current Fiscal Year		**Next Fiscal Year**	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$0.00	Total	$0.00

(b) What is the additional cost of the state rule?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$0.00	Total	$0.00

5. What is the total estimated cost by fiscal year to any private individual, private entity, or private business subject to the proposed, amended, or repealed rule? Please identify those subject to the rule, and explain how they are affected.

Current Fiscal Year	**Next Fiscal Year**
$ 0.00	$ 0.00

6. What is the total estimated cost by fiscal year to a state, county, or 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**
$ 0.00	$ 0.00

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.

ARKANSAS DEPARTMENT OF HEALTH

PHARMACY SERVICES AND DRUG CONTROL BRANCH

RULES ~~AND REGULATIONS~~ PERTAINING TO CONTROLLED SUBSTANCES

Effective Date: ~~December 1, 2014~~

Arkansas Department of Health
Renee Mallory, RN, BSN,
Secretary of Health

Jennifer Dillaha, MD
Director and State Health Officer

I, Nick Shull, Section Chief~~James Myatt, P.D., Director~~, Pharmacy Services and Drug Control, for the Arkansas Department of Health, do hereby certify that the documents attached hereto are true and correct copies of the current Rules ~~and Regulations~~ adopted by the Arkansas State Board of Health in accordance with Arkansas state law.

_____
Nick Shull, Section Chief~~James Myatt, P.D., Chief~~
Pharmacy Services and Drug Control

STATE OF ARKANSAS)
)
COUNTY OF PULASKI)

I, Marci Middleton-Yates~~Leslie Lovett~~, do hereby certify that Nick Shull, Pharm.D., ~~James Myatt, P.D.,~~ well known to me, appeared before me and signed the above referenced document.

Sworn and subscribed to before me this _____ day of _____, _____.~~24th day of October, 2014~~

_____
Notary Public

_____
My commission expires on

ARKANSAS DEPARTMENT OF HEALTH
RULES ~~AND REGULATIONS~~ PERTAINING TO CONTROLLED SUBSTANCES

Section I Authority

The following Rules ~~and Regulations~~ have been hereby promulgated pursuant, to Arkansas Code Annotated §5-64-702, §20-7-109, §20-64-219, and §20-64-317.

Section II Purpose

Drug abuse in Arkansas is a widespread problem. These rules ~~and regulations~~ have been prepared for the purpose of establishing a criterion for minimum standards of compliance in the prescribing, ordering, administration, dispensing, sale, and other means of legitimate handling of controlled substances. By necessity, they are of a regulatory nature, but are considered to be practical minimum design and operational standards. The rules ~~regulations~~ conform, insofar as practicable, with those promulgated at the Federal level.

Section III General Requirements

(Attached copy of Proposed Rules ~~and Regulations~~ of the Arkansas Department of Health Pertaining to Controlled Substances.)

Section IV Repeal

All Rules ~~and Regulations~~ and parts thereof in conflict herewith are hereby repealed.

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

CERTIFICATION

This will certify the Amendments 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 held in Morrilton, Arkansas, on the _____ ~~24th day of October, 2014~~, and after a Public Hearing on the _____ ~~2nd day of September, 2014~~, held in Little Rock, Arkansas, at the Department of Health Building.

~~Nathaniel Smith, M.D., MPH~~
Jennifer Dillaha, M.D.
Secretary of the State Board of Health
~~Arkansas State Board of Health~~

RULES ~~AND REGULATIONS~~
OF THE ARKANSAS DEPARTMENT OF HEALTH
PERTAINING TO CONTROLLED SUBSTANCES

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ARKANSAS DEPARTMENT OF HEALTH
RULES ~~AND REGULATIONS~~
PERTAINING TO CONTROLLED SUBSTANCES

SECTION I. REGISTRATION

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

A. A physician, podiatric physician, osteopathic physician, dentist, veterinarian, optometrist, scientific investigator, researcher, mid-level practitioner, or other persons licensed, registered, or otherwise permitted to prescribe, dispense, distribute, administer or conduct research with respect to controlled substances in the course of professional practice or research in Arkansas;

B. A pharmacy, hospital or related institution, manufacturer, wholesaler, distributor or other institution or facility, 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; or

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

D. 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, imported, exported, or dispensed.

SECTION II. EXEMPT PREPARATIONS

A. Schedule V Exempt Narcotics

A controlled substance listed in Schedule V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail provided, THAT:

(1) such dispensing is made only by a pharmacist and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

(2) not more than 240 cc (8 ounces) of any such controlled substance containing opium, nor more than 120 cc (4 ounces) of any other such controlled substance nor more than 48 dosage units of any such 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;

(3) the purchaser is at least 18 years of age;

(4) 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);

(5) a bound record book for dispensing of controlled substances under this Section is maintained by the pharmacist, which shall contain the name and address of the purchaser, the name and quantity of the controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of §21 CFR 1304.04); and

(6) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or Local law.

B. Ephedrine, Pseudoephedrine or Phenylpropanolamine

As provided in Ark. Code Ann. § 5-64-1101, et seq., unless dispensed under a valid prescription, all sales or transfers of ephedrine, pseudoephedrine or phenylpropanolamine, are subject to the following quantity limits and restrictions:

(1) In a single transaction, no more than three (3) packages of one (1) or more products that contain ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers;

(2) In a single transaction, no more than a single package of any product that contains ephedrine, pseudoephedrine, or phenylpropanolamine, that contains more than ninety-six (96) pills, tablets, gelcaps, capsules, or other individual units or more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, or a combination of any of these substances, whichever is smaller;

(3) In a single transaction, any product containing ephedrine, pseudoephedrine, or phenylpropanolamine, unless;

(a) The product is sold in a package size of not more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine base and is packaged in a blister pack, each blister containing not more than two (2) dosage units;

(b) When the use of a blister pack is technically infeasible, ~~that~~ the product is packaged in a unit dose packet or pouch; or

(c) In the case of a liquid, the drug is sold in a package size of not more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine base; or

(4) No product containing ephedrine, pseudoephedrine, or phenylpropanolamine may be sold or transferred to any person under eighteen (18) years of age, unless the person is purchasing an exempt product under Ark. Code Ann. § 5-64-1103 (b).

(5) No more than 5 grams of any product containing ephedrine or 9 grams of any product containing pseudoephedrine or phenylpropanolamine may be sold or transferred to a single patient in any 30 day period.

(6) A pharmacist, pharmacy or pharmacy employee must also comply with Federal law prohibiting the sale of more than 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine to a patient in any 24 hour period.

(7) The sale of such products shall be recorded in written or electronic format and shall document the signature and address of the purchaser (printed name if illegible), the name of the product and the quantity of the product purchased, the date of the purchase, and the signature of the Licensed Pharmacist or Registered Technician who issued the controlled substance to the purchaser; and

(8) All such records shall be maintained for a period of two (2) years from the last date of entry.

C. A pharmacist may not dispense and a pharmacy technician or intern may not sell or transfer ephedrine, pseudoephedrine, or phenylpropanolamine unless the patient has provided a driver's license or non-driver's identification card issued by the Department of Finance and Administration (DFA) that contains a photograph of the person, the person's date of birth, and a functioning magnetic stripe or bar code, or an identification card issued by the United States Department of Defense (DoD) to active duty military personnel that contains a photograph of the person and the person's date of birth. In addition to documenting the professional determination required by § 5-64-1103(c) and (d), a sale of ephedrine, pseudoephedrine, or phenylpropanolamine must also be approved

by scanning the license or identification card issued by DFA using the magnetic stripe or bar code, or by entering required information from the identification card issued by DoD into the real-time electronic logbook.

SECTION III. 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, V, and VI, shall be stored under double-lock security in a substantially constructed, permanently mounted cabinet. However, pharmacies may disperse controlled substances in Schedule II-V throughout the prescription area stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

SECTION IV. PROCEDURE IN CASE OF LOSS

A. Each practitioner that discovers any suspected loss, theft, ~~and/or~~ or other diversion, or any combination thereof, of any controlled substance shall immediately notify by phone or fax Pharmacy Services and Drug Control of the Arkansas Department of Health and the Arkansas State Board of Pharmacy. The nearest Drug Enforcement Administration (D.E.A.) Diversion Field Office must be notified in writing within one business day of the discovery of any suspected loss, theft or diversion. In addition, practitioners shall file theft and loss report~~s~~ D.E.A. Form 106 with Pharmacy Services and Drug Control of the Arkansas Department of Health, D.E.A., and the Arkansas State Board of Pharmacy within seven (7) days of the occurrence of said loss or the discovery of said loss.

B. Long-term care facilities (L.T.C.F.) that discover any suspected loss, theft, ~~and/or~~ or other diversion, or any combination thereof, of any controlled substance shall immediately notify Pharmacy Services and Drug Control of the Arkansas Department of Health by phone or fax. In addition, L.T.C.F.s shall file Arkansas Department of Health

theft and loss report form PHA-21 with Pharmacy Services and Drug Control of the Arkansas Department of Health.

SECTION V. CLASSIFICATION OF CONTROLLED SUBSTANCES

A. Pursuant to Ark. Code Ann. §5-64-201 et seq. the Director of the Arkansas Department of Health or designee 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.

B. 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 VI. RECORDS OF CONTROLLED SUBSTANCES

A. Every practitioner and L.T.C.F. shall keep a record of such controlled substances received, administered, dispensed or professionally used otherwise than by prescription in order to maintain complete accountability. The record shall in every case show the date of receipt, the name and address of the person or business from who received, and the kind and quantity of such controlled substances received.

B. The record shall show the controlled substances 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 controlled substances were sold, administered or dispensed or the owner and species of animal for which the controlled substances were sold, administered, or dispensed and the name, strength and quantity of controlled substances. Persons engaged in research on the use of controlled substances may withhold the name and other identifying characteristics of individuals who are the subjects of the research.

C. Institutional practitioner and L.T.C.F. records shall 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 is increased. The basic records of receipt and disposition of controlled substances within the institution are the patient medication records and the controlled substances procurement and disposition records.

(1) Patient medication records shall consist of at least (a) practitioners orders authorizing the dispensing and administration of medications, (b) medication administration record indicating the date, time, and signature of licensed person administering controlled substances to the patient and (c) the nurses notes indicating the date, time, and condition of the patient before and after the as needed controlled substance was administered and signature of the licensed person administering the controlled substance.

(2) In addition to patient medication records, a record of the procurement and disposition of a controlled substance shall be maintained.

(3) The disposition record shall reflect the actual dosage administered to the patient, the patient's name, date, time, and signature of the licensed person administering the controlled substance. Any error of entry on the disposition and procurement record shall follow a policy for correction of errors and accurate accountability. If the licensed person who procures the controlled substance is not the licensed person who administers the controlled substance, then both licensed persons shall sign the disposition record.

(4) When breakage or wastage of all or a partial dose of a controlled substance not in its original sealed package ~~and/or~~ or not administered to a patient occurs, the amount administered and the amount wasted shall be recorded by the licensed person who wasted the controlled substance and verified by the signature of another licensed

person who observed the wastage and how it was wasted. Controlled substances shall be wasted in such a manner that such substances are rendered unusable. (Licensed persons, in this paragraph, are those who are authorized by their current Practice Act to administer controlled substances, to include those licensed by the Arkansas State Medical Board, Arkansas State Board of Nursing, Arkansas State Board of Dental Examiners, Arkansas State Podiatry Examining Board, and the Arkansas State Board of Optometry. Licensed pharmacists and paramedics shall also be allowed to witness wastage of controlled substances.) ~~If a licensed person is not available to witness the wastage, the full or partial dose must be sent to Pharmacy Services and Drug Control for destruction.~~

(5) Records to include electronic signatures in a closed system (i.e. hospital) generated by automatic medication distribution devices shall comply with these ~~regulations~~ rules unless specifically exempted by Pharmacy Services and Drug Control. Policies and procedures shall be developed to ensure security and accountability of controlled substances and shall be approved administratively by Pharmacy Services and Drug Control prior to usage of such automatic medication distribution devices.

D. Each practitioner shall maintain inventory records in one consolidated record system of all controlled substances under the licensed practitioner's control and inventory shall be taken every two (2) years as required by the D.E.A.

E. Records of Schedule I and II substances shall be maintained separately from all other records. Records of Schedules III, IV, and V substances 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 for inspection and copying by authorized agents of Pharmacy Services and Drug Control of the Arkansas Department of Health. Every record shall be maintained by the registrant for at least two (2) years.

F. Adequate accountability does not require the use of a specific system or form, however the system employed shall be designed so that all record keeping requirements are met.

G. When an automated data processing system is used for the storage and retrieval of prescription orders for controlled substances, the system shall have the capability of generating a printout of all data which the user practitioner is responsible for maintaining under these ~~regulations~~ rules.

SECTION VII. SURRENDER OF UNWANTED CONTROLLED SUBSTANCES

A. All controlled substances no longer usable because of deterioration or expired dating or are unwanted, shall be delivered in person or by registered mail or by another means of shipment to allow for tracking from shipping point to destination with return receipt to: Pharmacy Services and Drug Control, Arkansas Department of Health, 4815 West Markham, Slot 25, Little Rock, Arkansas 72205-3867 accompanied by all completed copies of Report of Drugs Surrendered (Form PhA:DC-1) furnished by the Department of Health; or may be destroyed onsite only by authorized Agents of the Arkansas Department of Health.

B. Each controlled substance item submitted for destruction by ~~hospitals,~~ L.T.C.F.(s), or related facilities shall be submitted at least quarterly and each time there is a change in the licensed person responsible for discontinued or unwanted controlled substances and identified in such a manner to determine the exact location in the facility where it was last recorded in an accountability record to determine what person or persons had access or administered such controlled substances during the time it was in inventory in the facility.

C. In L.T.C.F.(s) all unwanted or discontinued controlled substances shall be entered on Surrender Form PhA:DC-1 at the time of transfer to the secured storage area. PhA:DC-1 requires the signature of two licensed persons verifying this transfer. Form PhA:DC-1 shall be securely and separately stored apart from all unwanted or discontinued controlled

substances. Accountability of discontinued controlled substances rests with the licensed person receiving the discontinued controlled substances until they are submitted to Pharmacy Services and Drug Control for destruction.

D. Non-D.E.A. registered licensed healthcare facilities shall develop policies and procedures to ensure that complete accountability is maintained on all controlled substances. Policies and procedures shall include specific licensed personnel responsible for unwanted or out-of-date controlled substances removed from use in the facility.

SECTION VIII. CONTROLLED DRUG PRESCRIPTION ~~/~~ OR ORDERS

A. Issue of Prescriptions or Orders

(1) The term prescription means an order for medication that is dispensed to or for an ultimate user but does not include an order for medication that is dispensed for immediate administration to the ultimate user. (~~e.g.~~ for example, an order to dispense a medication to a resident or patient for immediate administration in a licensed facility is not a prescription. However, the record keeping requirements of Section VI do apply to such orders.)

(2) A prescription or an order for controlled substances may be issued only by an individual practitioner who is legally authorized to prescribe or order controlled substances in the State of Arkansas and who holds a current Federal D.E.A. Registration.

(3) In settings where non-D.E.A. Registered Nurse Practitioners, Advance Practice Nurses, and Physicians Assistants are employed, a D.E.A. Registered Licensed Practitioner must determine the need for a controlled substance to be issued to a patient. Only the D.E.A. Registered Licensed Practitioner may then communicate the order to the pharmacist, either by written, oral, fax, or electronic prescription, if

issued in compliance with federal law and regulations. No standing orders or protocol for controlled substances shall be valid.

B. Purpose of Issue

(1) A prescription, in order to be effective, must be issued for legitimate medical purposes. The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

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

(3) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the individual prescribing practitioner. A practitioner shall sign a prescription in the same manner as he/she would sign a check or legal document. When an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential aspects to the law and regulations. A corresponding

liability rests upon the pharmacist who dispenses a prescription not prepared in the form prescribed in these ~~regulations~~ rules.

(4) An intern, resident or foreign-trained physician, or physician on the staff of a Veterans Administration facility, exempted from registration under ~~the Federal Act (~~21CFR §1301.24(c)~~)~~ shall include on all prescriptions issued by him/her, the registration number of the hospital or other institution and the special internal code number assigned to him/her by the hospital or other institution as provided, in lieu of the registration number of the practitioner as required by this section. Each written prescription shall have the name of the practitioner stamped, typed or printed on it as well as the signature in ink of the practitioner. In lieu of the registration number of the practitioner required by this section, all prescriptions issued shall include the branch of service or agency and service identification number.

C. Refilling of Prescriptions

(1) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

(2) No prescription for a controlled substance listed in Schedule III, IV, or V shall be dispensed or refilled more than six (6) months after the date on which the prescription was issued and no such prescription shall be authorized to be refilled more than five (5) times. Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document. If entered on another document, such as medication record, the document shall be uniformly maintained and readily retrievable. The following information shall be retrievable by the prescription number consisting of the name and dosage form of the controlled substance, the date dispensed or refilled, the quantity dispensed, initials of the dispensing pharmacist for each refill, and the total number of refills for that prescription. If the pharmacist

merely initials and dates the back of the prescription it shall be deemed that the full face amount of the prescription has been dispensed. The prescribing practitioner may authorize additional refills of Schedule III, IV, or V controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

(a) The total quantity authorized, including the amount of the original prescription, does not exceed five (5) refills nor extend beyond six (6) months from the date of issue of the original prescription.

(b) The pharmacist obtaining the oral authorization records on the reverse of the original prescription the date, quantity of refill, number of additional refills authorized, and initials the prescription showing who received the authorization from the prescribing practitioner who issued the original prescription.

(c) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(d) The prescribing practitioner shall execute a new and separate prescription for any additional quantities beyond the five (5) refills, six (6) month limitation.

(3) As an alternative to the procedures provided by subsection (2), an electronic data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III, IV, and V subject to the following conditions:

(a) Any such proposed electronic data processing system shall provide on-line retrieval (electronic record or hard-copy printout) of original prescription order information. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address and D.E.A.

registration number of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(b) Any such electronic data processing system must also provide on-line retrieval (electronic record of hard-copy printout) of the current refill history for Schedule III, IV, or V controlled substance prescription orders (those authorized for refill during the past six (6) months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for the prescription order.

(c) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV, or V controlled substance is correct shall be provided by the individual pharmacist who makes use of the system. If such a system provides a hard-copy printout of controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist shall verify that the data indicated is correct and then sign this document in the same manner he would sign a check or legal document (~~e.g.~~ for example, J.H. Smith or John H. Smith). This document shall be maintained in a separate file at the pharmacy for a period of two (2) years from the dispensing date. This printout of the day's controlled substance prescription order refill data shall be provided to each pharmacy using such an electronic data processing system within seventy-two (72) hours of the date on which the refill was dispensed. It shall be verified and signed by each pharmacist who is involved

with such dispensing. All required information shall be entered on the records of all prescription orders dispensed at the pharmacy including non-refillable prescriptions and shall be maintained for a period of no less than two (2) years. In lieu of such a printout, the pharmacy shall maintain a bound log book or separate file in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file shall be maintained at the pharmacy employing such a system for a period of two (2) years after the date of dispensing the appropriately authorized refill.

(d) Any such electronic data processing system shall have the capability of generating a printout of any refill data which the user pharmacy is responsible for maintaining under these ~~regulations~~ rules. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout shall include the name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any electronic data processing system employed by a user pharmacy the central record keeping location shall be capable of sending the printout to the pharmacy within forty-eight (48) hours, and if the Agent or Investigator requests a copy of such printout from the user pharmacy, it shall, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its system by documentation (~~e.g.~~ for example, postmark).

(e) In the event a pharmacy that employs such an electronic data processing system experiences down-time, the pharmacy shall have an approved auxiliary procedure which will be used for documentation of refills of Schedule III, IV, and V controlled substance prescription orders. This auxiliary procedure shall insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(f) When filing refill information for original prescription orders for Schedule III, IV, or V controlled substances, a pharmacy may use only one (1) of the two (2) systems described in this section.

D. Partial Dispensing of Prescriptions

(1) The partial dispensing of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

(a) Each partial dispensing is recorded in the same manner as the refilling,

(b) The total quantity dispensed in all partial dispensings does not exceed the total quantity prescribed, and

(c) No dispensing occurs six (6) months after the date on which the prescription was issued.

(2) The partial dispensing of a prescription for controlled substances 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/she makes a notation of the quantity supplied on the face of a written prescription (or written record of the emergency oral prescription) on the first partial dispensing. However, if the remaining portion is not or cannot be dispensed within a seventy-two (72) hour period, the pharmacist shall so

notify the prescribing individual practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

(3) A prescription for a Schedule II controlled substance written for a patient in a L.T.C.F. or for a patient with a medical diagnosis documenting a terminal illness may be dispensed 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 dispensing the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist shall record on the prescription whether the patient is *"terminally ill"* or an *"L.T.C.F. patient"*. Prior to any subsequent partial dispensing, the pharmacist shall determine the necessity of additional medication. For each partial dispensing, 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 dispensing, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial dispensings shall not exceed the total quantity prescribed. Schedule II prescriptions for patients in a L.T.C.F. or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by discontinuance of medication.

(4) Information pertaining to current Schedule II prescriptions for patients in a L.T.C.F. 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:

(a) Output (display or print) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the L.T.C.F. 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 dispensings that have been dispensed under each prescription and the information required in this Section.

(b) Immediate (real time) updating of the prescription record each time a partial dispensing of the prescription is concluded.

(c) Retrieval of partially-dispensed Schedule II prescription information is the same as required for Schedule III, IV, and V prescription refill information.

(5) The authority to dispense Schedule II prescriptions for partial quantities does not apply to other classes of patients; such as a patient with severe intractable pain who is not diagnosed as terminal.

E. Telephone or Oral Prescriptions

(1) In the case of an emergency situation, as defined by these ~~Regulations~~ Rules, 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 that patient during the emergency period, but never more than seventy-two (72) hours; (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:

(a) Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user;

(b) No appropriate alternative treatment is available (which includes the administration of a medication that is not a Schedule II medication); and

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

(2) The prescription shall be immediately reduced to writing by the pharmacist. Within seven days 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. The pharmacist must notify the nearest Drug Enforcement Administration if the prescribing individual practitioner fails to deliver a written prescription to him.

(3) A pharmacist may dispense a controlled substance listed in Schedule III, IV, or V pursuant to an oral prescription made by an individual practitioner or communicated by an employee or agent of the individual practitioner to a pharmacist. The pharmacist shall promptly either enter the prescription into the pharmacy's electronic prescription system or reduce it to writing. The prescription shall include all the information required in the case of a written prescription except for the written signature of the individual practitioner.

F. Prescription Transfers

(1) 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 (1) time basis only. However, pharmacies electronically sharing

a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

(a) The transfer is communicable directly between two (2) licensed pharmacists and the transferring pharmacist records the following information:

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

(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.

(2) The pharmacist receiving the transferred prescription information shall electronically record or reduce to writing the following:

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

(b) 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 and location of previous refill(s).

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

(vi) Name of pharmacist who transferred the prescription.

(c) The original and transferred prescription shall be maintained for a period of two (2) years from the date of last refill.

G. Facsimile

(1) A prescription for a Schedule II controlled substance may be transmitted by the prescribing practitioner to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraphs (2), (3), or (4) of this section. The original prescription shall be maintained in accordance with these rules ~~and regulations~~.

(2) A prescription prepared in accordance with these rules ~~and regulations~~ written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, subcutaneous, or intraspinal infusion may be transmitted by the prescribing practitioner to the home infusion pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph and it shall be maintained in accordance with these rules ~~and regulations~~.

(3) A prescription prepared in accordance with these rules ~~and regulations~~ written for a Schedule II substance for a resident of a L.T.C.F. may be transmitted by the prescribing individual practitioner to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph and it shall be maintained in accordance with these rules ~~and regulations~~.

(4) A prescription written for a Schedule II substance for a home hospice patient may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. It must be noted on the prescription that this is a hospice patient. The facsimile serves as the original written prescription.

(5) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V that is a prescription drug, only pursuant to either a written prescription signed

by a prescribing individual practitioner or a facsimile of a written signed prescription transmitted by the prescribing practitioner to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner and promptly either entered into the pharmacy's electronic prescription system or reduced to writing by the pharmacist, including all information required by these rules ~~and regulations~~, except for the signature of the prescribing practitioner.

(6) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to a facsimile of a written prescription or order for medication transmitted directly by the prescribing practitioner to the pharmacist, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist including all information required by these rules ~~and regulations~~, except for the signature of the individual practitioner or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

SECTION IX. SCHEDULE II PRESCRIPTIONS

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, except for patients classified as "terminally ill" or a "long term care patient".

SECTION X. VIOLATIONS

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

SECTION XI. SUSPENSION OR REVOCATION

A. 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~~ rules.

(2) The registrant has furnished false or fraudulent material or information in the application or renewal 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 failed to renew his/her registration within sixty (60) days after the registration expired.

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

SECTION XII. LABELING

A. Controlled substances dispensed by a practitioner to a patient shall bear a label that includes 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.

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

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