EXHIBIT D

DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION

SUBJECT: Controlled Substances

DESCRIPTION: The following changes are proposed:

Section VIII. Controlled Drug Prescription/Orders.

1. A.(3) – A DEA Registered Licensed Practitioner may communicate an order to the pharmacist, either by written, oral, faxed, or electronic prescription, if issued in compliance with federal law and regulations.

2. E.(3) – When a pharmacist dispenses a Schedule III, IV, or V controlled substance based upon an oral prescription, the pharmacist must promptly either enter the prescription into the pharmacy's electronic prescription system or reduce it to writing.

3. F.(2) – If a pharmacist receives a transferred prescription, the pharmacist shall electronically record or reduce to writing the required information identified in F.(2)(a) and (b).

4. G.(5) – When a pharmacist dispenses a Schedule III, IV, or V controlled substance based upon an oral prescription, the pharmacist must promptly either enter the prescription into the pharmacy's electronic prescription system or reduce it to writing.

PUBLIC COMMENT: A public hearing was held September 2, 2014. The public comment period expired September 2, 2014. The Department received the following public comments:

Clyde Frazier

COMMENT: Section V. Classification of Controlled Substances ---In Section A. (Page 6) the abbreviation et.seq. for "et sequentia" should be corrected to et seq. in two places. There should be no period after the et and there should be a space between the et and the seq.
RESPONSE: This change will be made.

COMMENT: Section VIII Part C Refilling of prescriptions (Page 13) ---In the second line from the top of the page there is a strikethrough of the word from. From should not be there, of course, but another word should replace it. Instead of from, the word should be FORM (to mean tablet, capsule, nasal spray, patch, etc.) Dosage FORM is consistent with the Federal wording at CFR 1306.22 (c) (1).
RESPONSE: This change will be made.

Isaac Linam, an attorney with the Bureau of Legislative Research, asked the following question:

QUESTION: Ark. Code Ann. § 5-64-308(b) specifically allows Schedules III and IV controlled substances to be dispensed with a prescription and prohibits refills more than six months after the prescription date. Ark. Code Ann. § 5-64-308(c) provides simply that a Schedule V controlled substance "shall not be distributed or dispensed other than for a medical purpose". In your rules, Schedules III, IV, ***and*** V, are treated the same relative to prescription requirements.

As such, why is Schedule V subject to the same prescription requirements as Schedules III and IV? Does the Department read the non-specificity of Ark. Code Ann. § 5-64-308(c) to give the Director broad discretion to make rules concerning the "distribut[ion] or dispens[ation]" of those drugs, so long as the "distribut[ion] or dispens[ation]" is "for a medical purpose"?

RESPONSE: Some schedule V products such as codeine containing cough syrups can be distributed or dispensed without a prescription by the pharmacist if the pharmacist makes the determination that it is for a legitimate medical purpose. If a doctor issues a prescription for a schedule V drug, then it falls under the same requirements for issuance of a prescription.

It is our opinion that the lack of specificity, combined with the director's broad authority give us the ability to make rules concerning dispensing and distributing these drugs.

The proposed effective date for the rule is December 1, 2014.

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: Ark. Code Ann. § 20-7-109 authorizes the State Board of Health to promulgate rules for the "protection of the public health and safety".

The Director of the Department of Health shall administer the Uniform Controlled Substances Act, Ark. Code Ann. § 5-64-101 et seq., and may add a substance to or delete or reschedule any substance enumerated in a schedule under the procedures of the Arkansas Administrative Procedure Act. Ark. Code Ann. § 5-64-201(a)(1)(A)(i).

Ark. Code Ann. § 5-64-702 authorizes the Department of Health to promulgate rules to enforce the controlled substance laws.

This rule implements Acts 2013, No. 1331. Act 1331 amended Ark. Code Ann. § 5-64-308 to make clear that a practitioner may prescribe controlled substances electronically.

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

DEPARTMENT/AGENCY Department of Health

DIVISION Center for Health Protection

DIVISION DIRECTOR Donnie Smith

CONTACT PERSON James Myatt, PD

ADDRESS 4815 West Markham, Slot 31, Little Rock, AR 72205

PHONE NO. 501-661-2325 **FAX NO.** 501-661-2769 **E-MAIL** james.myatt@arkansas.gov

NAME OF PRESENTER AT COMMITTEE MEETING James Myatt, PD

PRESENTER E-MAIL james.myatt@arkansas.gov

INSTRUCTIONS

A. Please make copies of this form for future use.
B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

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1. What is the short title of this rule? Rules and Regulations Pertaining to Controlled Substances

2. What is the subject of the proposed rule? Amending current rules pursuant to Act 1331 of 2013 regarding electronic prescribing of controlled substances

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☐ No ☒
   If yes, please provide the federal rule, regulation, and/or statute citation. _____

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes ☐ No ☒
   If yes, what is the effective date of the emergency rule? _____

   When does the emergency rule expire? _____

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes ☐ No ☐

5. Is this a new rule? Yes ☐ No ☒
If yes, please provide a brief summary explaining the regulation. _____

Does this repeal an existing rule? Yes ☐ No ☒
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. _____

Is this an amendment to an existing rule? Yes ☒ No ☐
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Ark. Code Ann. § 5-64-201; Ark. Code Ann. § 20-7-109, Act 588 of 2011

7. What is the purpose of this proposed rule? Why is it necessary? It is necessary to update the regulations to incorporate changes enacted in Act 1331 of 2013 related to electronic prescribing of controlled substances

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).
http://www.healthy.arkansas.gov/aboutADH/Pages/RulesRegulationsProposed.aspx

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐
If yes, please complete the following:

Date: September 2, 2014
Time: 10:00 a.m.
Place: Arkansas Department of Health, Room 2508, 4815 West Markham, Little Rock, AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
September 2, 2014

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
December 1, 2014

12. Do you expect this rule to be controversial? Yes ☐ No ☒
If yes, please explain. _____

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

Arkansas State Board of Pharmacy, Arkansas State Board of Nursing, Arkansas Medical Board, Arkansas Medical Society, Arkansas Pharmacists Association, Arkansas Board of Dental Examiners, Arkansas Board of Optometry, Arkansas Podiatry Examining Board, Arkansas Veterinary Medical Examining Board, Office of Prosecutor Coordinator, Arkansas Department of Human Services, Health Facility Services Arkansas Department of Health, Arkansas State Crime Laboratory, Drug Enforcement Admnistration

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Health
DIVISION Center for Health Protection, Pharmacy Services and Drug Control Branch
PERSON COMPLETING THIS STATEMENT James Myatt, PD
TELEPHONE NO. 501-661-2325 **FAX NO.** 501-661-2769 **EMAIL:** james.myatt@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 Rules and Regulations Pertaining to 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 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		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	

Total _____ Total _____

(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	_____	Total	_____

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.