

EXHIBIT E

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

DEPARTMENT/AGENCY Arkansas Department of Health
DIVISION Center for Health Protection
DIVISION DIRECTOR Donnie Smith
CONTACT PERSON James Myatt
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NAME OF PRESENTER AT COMMITTEE MEETING Robert Brech
PRESENTER E-MAIL robert.brech@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

1. What is the short title of this rule? Rules and Regulations Pertaining to the List of Controlled Substances for the State of Arkansas
2. What is the subject of the proposed rule? Hydrocodone Combination Products are being rescheduled from a Schedule III substance to a Schedule II substance. Also, prostanazol and methasterone are being added to Schedule III. Both changes are being done pursuant to the DEA's federal List 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. 21 C.F.R. § 1308 (HCP) & 21 U.S.C. § 813
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If yes, a copy of the repealed rule is to be included with your completed questionnaire.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 et seq.

7. What is the purpose of this proposed rule? Why is it necessary? This Rule change is to reschedule Hydrocodone Combinations Products from a Schedule III to a Schedule II and to add prostanazol and methasterone to Schedule III, so that the Arkansas List for Controlled Substances continues to mirror the Federal List for 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). www.healthy.arkansas.gov

9. Will a public hearing be held on this proposed rule? Yes No

If yes, please complete the following:

Date: November 14, 2014

Time: 10:00 a.m.

4815 West Markham, L137

Place: Little Rock, AR

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

December 1, 2014

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

May 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.
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FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health
DIVISION Center for Health Protection
PERSON COMPLETING THIS STATEMENT Elizabeth Pitman
TELEPHONE NO. (501) 280-4034 **FAX NO.** (501) 661-2357 **EMAIL:** sarah.pitman@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 the List of Controlled Substances for the State of Arkansas

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

General Revenue	<u>0</u>
Federal Funds	<u>0</u>
Cash Funds	<u>0</u>
Special Revenue	<u>0</u>
Other (Identify)	<u>0</u>

Next Fiscal Year

General Revenue	<u>0</u>
Federal Funds	<u>0</u>
Cash Funds	<u>0</u>
Special Revenue	<u>0</u>
Other (Identify)	<u>0</u>

Total 0

Total 0

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

Current Fiscal Year

General Revenue 0
Federal Funds 0
Cash Funds 0
Special Revenue 0
Other (Identify) 0

Total 0

Next Fiscal Year

General Revenue 0
Federal Funds 0
Cash Funds 0
Special Revenue 0
Other (Identify) 0

Total 0

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

Current Fiscal Year

\$ 0

Next Fiscal Year

\$ 0

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

\$ 0

Next Fiscal Year

\$ 0

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

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000

Governor Mike Beebe

Nathaniel Smith, MD, MPH, Director and State Health Officer

SUMMARY OF PROPOSED AMENDMENTS TO THE RULES AND REGULATIONS PERTAINING TO THE LIST OF CONTROLLED SUBSTANCES FOR THE STATE OF ARKANSAS

The following changes are being made to the Rules and Regulations Pertaining to the List of Controlled Substances for the State of Arkansas:

1. Hydrocodone combination products (HCPs) are being permanently rescheduled from a Schedule III to a Schedule II based upon the notice of final rulemaking issued by the DEA on August 22, 2014. This change went into effect in Arkansas by emergency rulemaking on October 6, 2014, and this proposed amendment will make that emergency rule effective. The rule will allow the refill of valid prescriptions until April 8, 2015.
2. Prostanazol and methasterone are being added to Schedule III to mirror the DEA's controlled substance list.

These changes are being made based on comments received during the last rulemaking process.