

Exhibit E

DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION

SUBJECT: List of Controlled Substances

DESCRIPTION: The following additions are proposed to the list:

On June 17, 2014, Dr. Nathaniel Smith, Director and State Health Officer, determined that methyl-N-ethylcathinone or MEC posed an imminent peril to the public health, safety, or welfare and immediately classified the substance as Schedule I pursuant to Ark. Code Ann. § 5-64-201. The department was notified by the Fourth Judicial District, Washington and Madison Counties, Deputy Prosecuting Attorney, that the substance was found in a synthetic stimulant product tested by the Arkansas State Crime Lab.

Since the last update of the List of Controlled Substances, the Department of Justice Drug Enforcement Agency (DEA) has added Perampanel to Schedule III and Alfaxalone to Schedule IV.

Due to the evidence of its threat to the public's health, the department is adding etizolam to Schedule I. Etizolam is a benzodiazepine derivative that has not been approved for use in the United States. Benzodiazepine-related drugs are among the most commonly abused medications in the U. S. Etizolam is known to be available in Arkansas via the Internet.

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: Schedule IV of your current List includes a section titled (f) Other Substances. On page 15 of 20 of the 7-14-2014 Mark-Up item #2 is carisoprodol. Carisoprodol was scheduled federally in 2012 and is now listed under Depressants just below camazepam with an ID number of 8192. Even though the drug has been controlled by the State of Arkansas since April 1997, Ark. Code Ann. 5-64-201 (d) requires that any substance designated as a controlled substance under federal law is to be similarly controlled in Arkansas 30 days after publication in the Federal Register. The scheduling rule was published in the Federal Register on December 12, 2011 with an effective date of January 11, 2012. In all past Lists of Controlled Substances for the State of Arkansas when "similarly controlled" the drug has been listed as in the Federal document (i.e. proper category, DEA ID number, and date of scheduling) I suggest that carisoprodol be similarly controlled in compliance with Ark. Code Ann. 5-64-201(d).

RESPONSE: This change will be made.

COMMENT: To save performing a similar task in the future, I would also state that Schedule IV of your current list includes a section titled (f) Other Substances. On page 15 of 20 of the 7-14-2014 Mark-Up item #5 is tramadol. Tramadol was scheduled federally just recently and is now listed under Depressants just below tetrazepam with an

ID number of 9752. Even though the drug has been controlled by the State of Arkansas since August 2007, Ark. Code Ann. 5-64-201 (d) requires that any substance designated as a controlled substance under federal law is to be similarly controlled in Arkansas 30 days after publication in the Federal Register. The effective date of this scheduling of tramadol is August 18, 2014. So there is still time to add this to the list before the September Public Hearing. Again, in all past Lists, when “similarly controlled” the drug has been listed as in the Federal Register (i.e. proper category, DEA ID number, and date of scheduling) I suggest that tramadol be similarly controlled in compliance with Ark. Code Ann. 5-64-201 (d).

RESPONSE: This change will be made.

COMMENT: I should also mention that other drug entities might need to be considered for inclusion in the List. Prostanazol and methasterone are now classified as Schedule III anabolic steroids by the DEA with effective dates of 2012 (See 7-2-2014 current DEA list). Some of the “exempted” estrogen/ methyltestosterone products are also now Schedule III. And I did not see the date of scheduling noted beside lorcaserin in Schedule IV of the Arkansas List.

RESPONSE: Prostanazol and methasterone will be added to Schedule III. We will continue to follow DEA’s exempt product list. The date will be added beside lorcaserin.

Corporal Paul M. Smith

COMMENT: I request that the DEA hydrocodone change which reschedules drugs that contain both hydrocodone and other substances such as acetaminophen or aspirin from Schedule III to Schedule II be incorporated into the currently proposed state controlled substances list. Criminal cases cite the state’s controlled substance list. The federal change is effective October 6, which is prior to the anticipated effective date for the proposed list.

RESPONSE: This change will be made.

The proposed effective date for the final 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. § 5-64-201(d) directs the Department to control a substance “after the expiration of thirty (30) days from publication in the Federal Register” if the substance is designated as a controlled substance under federal law. Ark. Code Ann. § 5-64-201(d)

allows the Director to object to inclusion if the Director publishes the reason for the rejection and affords an interested party an opportunity for a hearing.

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

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

- 1. What is the short title of this rule? Rules and Regulations Pertaining to List of Controlled Substances for the State of Arkansas

- 2. What is the subject of the proposed rule? Amending current rules to add drugs to the 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. _____

- 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 include drugs recently determined to meet the need for regulation due to potential for abuse or threat to public health

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.

Arkansas Department of Health, Room
2508, 4815 West Markham, Little

Place: 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 Administration

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 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

Next Fiscal Year

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

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
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 _____

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 _____

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.