DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION

SUBJECT: List of Controlled Substances

DESCRIPTION: The proposed amendments update the List of Controlled Substances to include four drugs:

1. Mitragynine – The Department was notified by Dr. Thomas Atkinson, M.D., Springdale Treatment Center, Springdale, AR, that same of the patients at his Addiction Treatment Center indicated that they used this drug which is derived from a plant known as Kratom. Dr. Atkinson indicated that the drug exhibited an opiate agonist action and that the patients had purchased Kratom at local businesses. This drug would be included as Schedule 1, (page 2, c, 24) since it has no recognized medical use by the FDA.

2. 7-hydroxymitragynine – The other active drug derived from kratom. This drug would also be included as Schedule 1 (page 2, c, 25).

3. Alpha-pyrrolidinopentiophenone (alpha-PVP) – Rick Hogan, General Counsel, Department of Health, received information regarding this synthetic stimulant known to cause violent behavior that the DEA has temporarily banned. This drug would be included as Schedule 1 (page 5, b, 8).

4. Suvorexant – The FDA approved this drug for the treatment of insomnia. To follow the DEA, this drug would be included as a Schedule IV controlled substance (page 14, c, 56).

PUBLIC COMMENT: A public hearing was held on September 1, 2015. The Public Comment period expired on September 1, 2015. The Department did not receive any public comments.

The proposed effective date is February 1, 2016.

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION:

Ark. Code Ann. § 5-64-201 (a)(1)(A)(i) gives the Director of the Department the authority to add or delete or reschedule any substance enumerated in a schedule.

Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000
Governor Asa Hutchison
Nathaniel Smith, MD, MPH, Director and State Health Officer

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

The proposed amendments update the List of Controlled Substances to include four drugs.

1. Mitragynine; The Department was notified by Dr. Thomas Atkinson, M.D., Springdale Treatment Center, Springdale, AR, that some of the patients at his Addiction Treatment Center indicated they used this drug which is derived from a plant known as *Kratom*. Dr. Atkinson indicated that the drug exhibited an opiate agonist action and that the patients had purchased *Kratom* at local businesses. This drug would be included as Schedule 1 (page 2, c, 24) since it has no recognized medical use by the FDA.

2. 7-hydroxymitragynine; The other active drug derived from *Kratom*. This drug would also be included as Schedule 1 (page 2, c, 25).

3. Alpha-pyrrolidinopentiophenone (alpha-PVP); Rick Hogan, General Counsel, Arkansas Department of Health, received information regarding this synthetic stimulant known to cause violent behavior that the DEA has temporarily banned. This drug would be included as Schedule 1 (page 5, b, 8).

4. Suvorexant; The FDA approved this drug for the treatment of insomnia. To follow the DEA, this drug would be included as a Schedule IV controlled substance (page 14, c, 56).

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 Renee Mallory

CONTACT PERSON James Myatt

ADDRESS 4815 West Markham St., Slot 25, Little Rock, Arkansas 72205

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

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? Regular scheduling of Mitragynine and 7-hydroxymitragynine as Schedule 1 pursuant to a request by Dr. Thomas Atkinson, M.D., Springdale Treatment Center, Springdale, AR. Regular scheduling of alpha-pyrrolidinopentiophenone (alpha-PVP) as Schedule 1 pursuant to information received by the Arkansas Department of Health and Drug Enforcement Administration action to temporarily ban this drug. Regular scheduling of Suvorexant as Schedule IV to follow Drug Enforcemet Administration scheduling.

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☒ No ☐ Partially. The Scheduling of Suvorexant is to follow the DEA scheduling of the same drug so that the lists remain consistent.

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. A.C.A. 5-64-201

7. What is the purpose of this proposed rule? Why is it necessary? Mitragynine and 7-hydroxymitragynine exhibit opiate like activitity when consumed. Alpha-PVP is a stimulant know to cause violet behaviour when consumed. Suvorexant has been approved by the FDA for the treatment of insomnia.

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.arkansas.gov

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

Date: September 1, 2015
Time: 10:00 A.M.
Place: Arkansas Dept. of Health, 4815 West Markham, Little Rock, AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
September 1, 2015

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

February 1, 2016

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.

Prosecuting Attorneys in Arkansas-for

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		**Next Fiscal Year**	
General Revenue	0	General Revenue	0
Federal Funds	0	Federal Funds	0
Cash Funds	0	Cash Funds	0
Special Revenue	0	Special Revenue	0
Other (Identify)	0	Other (Identify)	0

Total	0	Total	0

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

Current Fiscal Year		Next Fiscal Year	
General Revenue	0	General Revenue	0
Federal Funds	0	Federal Funds	0
Cash Funds	0	Cash Funds	0
Special Revenue	0	Special Revenue	0
Other (Identify)	0	Other (Identify)	0
Total	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	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.