

EXHIBIT L

DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION/PHARMACY SERVICES

SUBJECT: List of Controlled Substances

DESCRIPTION: This adds substances to the controlled substance list that the DEA listed or the State Crime Laboratory has requested be listed.

The updated list includes these drugs:

1. 25B-NBOMe. 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine. The DEA has placed this hallucinogenic substance into Schedule I because it has no recognized medical use. To follow DEA scheduling, this drug would be included as Schedule 1, page 5 (46).
2. AB-FUBINICA. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide. The DEA has scheduled this synthetic cannabinoid because it has no recognized medical use. This drug would be included as Schedule IV., page 19, I, (ix).
3. ADB-PINACA. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide. The DEA has scheduled this synthetic cannabinoid because it has no recognized medical use. This drug would be included as Schedule VI, page 19, I (x).
4. The DEA has scheduled the following synthetic cathinones as Schedule I because they have no medical use. These drugs will be included as Schedule I, page 6, 11b, 9-16:
4-methyl-N-ethylcathinone (4-MEC)
4-methyl-alpha-pyrrolidinopropiophenone (4-MePPP)
2-(methylamino)-1-phenylpentan-1-one (Pentadrone)
1-(1,3-benzodioxol-5-yl)-2-(methylamino) pentan-1-one (Pentylone, MDBP)
4-fluoro-N-methylcathinone (4-FMC, Flephedrone)
3-fluoro-N-methylcathinone (3-FMC)
1-(naphthalene-2-yl)-2-(pyrrolidin-1-yl) pentan-1-one (Naphyrone)
Alpha-pyrrolidinobutiophenone [(Alpha)-PBP].
5. 5-Fluoro-AMB. N-[[1-(5-fluoropentyl)-1H-indazol-3-yl] carbonyl]]-L-valine, methyl ester. Page 20, (K) (xvi). Felsia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this synthetic cannabinoid with no recognized medical use be included into Schedule VI, page 20, (K), xvi.
6. MMB-CHMICA. Methyl [1-(cyclohexylmethyl)-1H-indole-3-carbonyl] (Felsia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this synthetic cannabinoid with no recognized medical use be included into Schedule VI, page 20, (K), xvii.

7. To follow Act 440 of 2017, language is added on page 21 (c) (1) to consider the designation, rescheduling, or descheduling of a marijuana derived substance. This will allow the scheduling if FDA approves cannabidiol and other substances to be prescribed to treat medical conditions. Page 21, (c) (1).

PUBLIC COMMENT: A public hearing was held on December 5, 2017, and the public comment period expired on the same date. No public comments were submitted to the Department regarding the proposed rule. The proposed effective date is March 1, 2018.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: A “controlled substance” is a drug, substance, or immediate precursor in Schedules I through VI. *See* Ark. Code Ann. §5-64-101(4) (Repl. 2016). The Director of the Department of Health may “add a substance to or delete or reschedule any substance enumerated in a schedule pursuant to the procedures of the Arkansas Administrative Procedure Act[.]” *See* Ark. Code Ann. §5-64-201(a)(1)(A)(i) (Supp. 2017). If any substance is designated as a controlled substance under federal law and notice of the designation is given to the Director, the Director shall similarly control the substance unless the Director objects to the inclusion. *See* Ark. Code Ann. §5-64-201(d)(1) (Supp. 2017).

Additional authority is provided by Act 440 of 2017, sponsored by Representative Justin Boyd, to allow for potential future recognition of a legal marijuana-derived Schedule VI controlled substance. If notice has been given to the Director that the United States Food and Drug Administration has designated, rescheduled, or de-scheduled a marijuana-derived substance as a prescription medication, the Director shall consider the designation, rescheduling, or descheduling of the marijuana-derived substance. *See* Ark Code Ann. §5-64-201(d)(4) (Supp. 2017).

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

DEPARTMENT/AGENCY Department of Health
DIVISION Center for Health Protection/Pharmacy Services
DIVISION DIRECTOR Renee Mallory
CONTACT PERSON Robert Brech
ADDRESS 4815 West Markham, Slot 31, Little Rock, AR 72205
PHONE NO. 501-661-2297 FAX NO. 501-661-2357 E-MAIL robert.brech@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

RECEIVED

NOV 03 2017

BUREAU OF LEGISLATIVE RESEARCH

- *****
1. What is the short title of this rule? List of Controlled Substances
 2. What is the subject of the proposed rule? Controlled substances
 3. Is this rule required to comply with a federal statute, rule, or regulation? Yes No X
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 X
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

7. What is the purpose of this proposed rule? Why is it necessary? To add substances to the controlled substance list that the DEA listed or the state crime laboratory has requested be listed.

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: FBD 12-5-17

Time: 10:00 a.m.

Place: Rm 2512, 4815 W. Markham, Little Rock

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

FBD 12-5-17

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

March 1, 2018

12. Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice. _____

13. Please provide proof of filing the rule with the Secretary of State and the Arkansas State Library as required pursuant to Ark. Code Ann. § 25-15-204(e). _____

14. 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. _____

FINANCIAL IMPACT STATEMENT

RECEIVED

PLEASE ANSWER ALL QUESTIONS COMPLETELY

NOV 03 2017

DEPARTMENT Department of Health

DIVISION Center for Health Protection/Pharmacy Services

PERSON COMPLETING THIS STATEMENT Robert Brech

TELEPHONE 501-661-2297 **FAX** 501-661-2357 **EMAIL:** Robert.brech@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 List of 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?

<u>Current Fiscal Year</u>		<u>Next Fiscal Year</u>	
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 _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total \$0 _____

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