EXHIBIT I

DEPARTMENT OF HEALTH, PHARMACY SERVICES AND DRUG CONTROL

SUBJECT: List of Controlled Substances

DESCRIPTION: The proposed amendments update the List of Controlled Substances as follows:

- Updated prefatory language for Schedule I Opiates. To follow DEA, ¶ (b)(34) is removed and replaced with 3-methylthiofentanyl. Page 1, (b).
- Furanyl fentanyl is a Schedule I controlled substance. To follow DEA, a DEA Controlled Substance Code Number has been set forth opposite of this substance. Page 2, (61).
- Ocfentanil is a Schedule I controlled substance. To follow DEA, a DEA Controlled Substance Code Number has been set forth opposing of this substance. In addition, this item has been marked for cleanup. Page 2, (63).
- The DEA has placed the following opioid analgesics into Schedule I because they have no recognized medical use. To follow DEA scheduling, these drugs would be included as Schedule I:
    - Acryl fentanyl. Page 3, (72).
    - 4-fluoroisobutyryl fentanyl. Page 3, (73).
    - Tetrahydrofuranyl fentanyl. Page 3, (74).
- 5-Methoxy-DALT. Felisia Lackey, Chief Forensic Chemist – Drug Section, Arkansas State Crime Laboratory, requested the listing of an additional trade or other name for N,N-Diallyl-5-Methoxytryptamine. Page 5, (34).
- 4-anilino-N-phenethylpiperidine (ANPP). The DEA has corrected the name of this immediate precursor to fentanyl. To follow DEA, this Schedule II substance name has been corrected. In addition, language identifying this substance has been marked for cleanup. Page 9, (g)(3).
- Methandrostenolone is relocated from page 12, (f)(16) and placed on the same line as methandienone located on page 12, (f)(13). Felisia Lackey, Chief Forensic Chemist – Drug Section, Arkansas State Crime Laboratory, requested listing methandienone and methandrostenolone together as they are different names for the same Schedule III anabolic steroid. Both names are listed on the same line with subsequent numbering corrections. Page 12, (f)(13).
- Pursuant to Act 504, Ark. Code Ann. § 5-64-215(a)(2), concerning substances in Schedule VI, is amended. The section additions for Tetrahydrocannabinol are as follows:
    - Tetrahydrocannabinols, unless the tetrahydrocannabinol is:
        A. Contained in hemp-derived cannabidiol;
        B. Not more than three-tenths of one percent (0.3%) of the hemp-derived cannabidiol on a dry weight basis as verified by a nationally accredited laboratory for quality, purity and accuracy standards; and
        C. Not approved by the United States Food and Drug Administration for marketing as a medication.

- 2NE1 is removed from page 20, (I)(iii) and placed with JWH-018 adamantyl carboxamide on page 20, (I)(iv). Felisia Lackey, Chief Forensic Chemist – Drug Section, Arkansas State Crime Laboratory, requested listing JWH-018 adamantyl carboxamide and 2NE1 together as they are both names for the same synthetic cannabinoid substance. Both names will be listed on the same line with subsequent numbering corrections. Page 20, (I)(iii).
- AKB-48 is a Schedule VI substance listed in two classification sections for synthetic cannabinoids. Felisia Lackey, Chief Forensic Chemist – Drug Section, Arkansas State Crime Laboratory, requested the removal of AKB-48 from Section K for synthetic cannabinoids. Subsequent numbering corrections will follow the removal of AKB-48 from Section K. This substance will remain in Section I for Schedule VI synthetic cannabinoids. Page 20, (I)(iv).
- Two items have been marked for cleanup on page 21: item (K)(xxii) and item (K)(xxiii).
- MAB-CHMINACA, AB-FUBINACA, and ADB-PINACA are Schedule VI synthetic cannabinoids currently on the controlled substances list. Felisia Lackey, Chief Forensic Chemist – Drug Section, Arkansas State Crime Laboratory, requested that these substances be removed from Section I and placed in Section K for synthetic cannabinoids. These substances are listed as:
    - MAB-CHMINACA. Page 21, (K)(xxiv).
    - AB-FUBINACA. Page 22, (K)(xxv). This item is also marked for cleanup.
    - ADB-PINACA. Page 22, (K)(xxvi).
    - 5F-CUMYL-PINACA. Felisia Lackey, Chief Forensic Chemist – Drug Section, Arkansas State Crime Laboratory, requested that this synthetic cannabinoid substance with no recognized medical use be included in Schedule VI. Page 22, (K)(xxvii).

PUBLIC COMMENT: A public hearing was held on this rule on September 26, 2019. The public comment period expired September 26, 2019. The agency indicated that it did not receive any public comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The agency indicated that this amended rule does not have a financial impact.

LEGAL AUTHORIZATION: The Department of Health administers the Uniform Controlled Substances Act and has authority to add substances to the Controlled Substances List and to delete or reschedule "any substance enumerated in a schedule[.]" Ark. Code Ann. § 5-64-201(a)(1)(A)(i). If a substance is controlled under federal law, the Department "shall similarly control the substance" unless the Secretary of the Department objects to inclusion within thirty days of publication in the Federal Register of a final order designating a substance as a controlled substance. Ark. Code Ann. § 5-64-201(d).

QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Arkansas Department of Health

DIVISION Pharmacy Services and Drug Control

DIVISION DIRECTOR Marisha DiCarlo, PhD.

CONTACT PERSON Shane David, Pharm.D.

ADDRESS 4815 West Markham Slot 25 Little Rock, AR 72205

PHONE NO. 501-661-2325 **FAX NO.** 501-661-2796 **E-MAIL** shane.david@arkansas.gov

NAME OF PRESENTER AT COMMITTEE MEETING Shane David, Pharm.D.

PRESENTER E-MAIL shane.david@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:

Jessica C. Sutton
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? List of Controlled Substances

2. What is the subject of the proposed rule? The scheduling of 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? N/A

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes_____ No_X_____

5. Is this a new rule? Yes_____ No_X____

If yes, please provide a brief summary explaining the rule.

Does this repeal an existing rule? Yes_____No_X_____ 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_X___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 - 5-64-2016

7. What is the purpose of this proposed rule? Why is it necessary?

Update the List of Controlled Substances for the State of Arkansas

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.healthyarkansas.com/rules_regs/rules_regs.htm

9. Will a public hearing be held on this proposed rule? Yes_X____No_____
If yes, please complete the following:

Date: September 26, 2019

Time: 10:00 am

Place: 1st Floor, Room L 357, 4815 West Markham St, Little Rock

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

September 26, 2019

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

N/A

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 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.

Not Known

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health
DIVISION Pharmacy Services and Drug Control
PERSON COMPLETING THIS STATEMENT Shane David, Pharm.D.
TELEPHONE NO. 501-661-2325 **FAX NO.** 501-661-2769 **EMAIL:** shane.david@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 X

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 X 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 X 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.

6. 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

That might occur for those selling the product

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 X____

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

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

The proposed listed amendments update List of Controlled Substances to include these drugs.

1. Updated prefatory language for Schedule I Opiates. Page 1, (b). To follow DEA, *paragraph (b) (34)* is removed and replaced with *3-methylthiofentanyl*. Page 1, (b).

2. Furanyl fentanyl is a Schedule I controlled substance. Page 2, (61). To follow DEA, a DEA Controlled Substance Code Number has been set forth opposite of this substance. Page 2, (61).

3. Ocfentanil is a Schedule I controlled substance. Page 2, (63). To follow DEA, a DEA Controlled Substance Code Number has been set forth opposite of this substance. In addition, this item has been marked for clean-up. Page 2, (63).

4. Acryl fentanyl. N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide. The DEA has placed this opioid analgesic into Schedule I because it has no recognized medical use. To follow DEA scheduling, this drug would be included as Schedule I. Page 3, (72).

5. 4-Fluoroisobutyryl fentanyl. N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl) isobutyramide. The DEA has placed this opioid analgesic into Schedule I because it has no recognized medical use. To follow DEA scheduling, this drug would be included as Schedule I. Page 3, (73).

6. Tetrahydrofuranyl fentanyl. N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide. The DEA has placed this opioid analgesic into Schedule I because it has no recognized medical use. To follow DEA scheduling, this drug would be included as Schedule I. Page 3, (74).

7. 5-Methoxy-DALT. Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested the listing of an additional trade or other name for N,N-Diallyl-5-Methoxytryptamine. Page 5, (34).

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    (2) Tetrahydrocannabinols, *unless the tetrahydrocannabinol is:*

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13. Two items marked for clean-up:
    - Page 21, (K), (xxii),
    - Page 21, (K), (xxiii).

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    - MAB-CHMINACA. Page 21, (K), (xxiv),
    - AB-FUBINACA. Page 22, (K), (xxv), this item is also marked for clean-up,
    - ADB-PINACA. Page 22, (K), (xxvi).

15. 5F-CUMYL-PINACA. 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide. Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this synthetic cannabinoid substance with no recognized medical use be included into Schedule VI. Page 22, (K), (xxvii).