QUESTIONNAIRE
FOR FILING PROPOSED RULES WITH THE
ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Department of Health
DIVISION Pharmacy Services
DIVISION DIRECTOR Shane David, Pharm.D., Section Chief
CONTACT PERSON Laura Shue, General Counsel
ADDRESS 4815 West Markham, Slot 31 Little Rock, AR 72205
PHONE NO. (501) 661-2297 **FAX NO.** (501) 661-2357 **E-MAIL** laura.shue@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Laura Shue, General Counsel
PRESENTER E-MAIL laura.shue@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
D. Rule" below.
E. Submit two (2) copies of the 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 for the State of Arkansas

2. What is the subject of the proposed rule? Schedules 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 rule.**

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 Yes ☐ No ☑ If yes, a copy of the repealed rule is to be included with your completed questionnaire.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."

Attached summary shows the proposed revisions and amendments.

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(a)(1)(A)(i) and (d)(4); §5-64-216

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

Arkansas law requires the Secretary of Health to revise and publish the schedules annually. Certain substances have been determined to have a potential for abuse and have no medical use. Additional substances have been designated as a controlled substance or descheduled under federal law and Arkansas law requires the substance to be similarly controlled.

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/proposed-amendment-to-existing-rules

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

Date: 12/15/2020

Time: 10:00 AM

Place: The Auditorium of the Arkansas Department of Health building at 4815 West Markham, Little Rock, Arkansas, 72205

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

12/15/2020

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

05/30/2021

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.**

None, no known opposition.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Health
DIVISION Pharmacy Services
PERSON COMPLETING THIS STATEMENT
TELEPHONE NO. (501) 661-2297 **FAX NO.** (501) 661-2357 **EMAIL:** laura.shue@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two (2) copies with the Questionnaire and proposed rules.

SHORT TITLE OF THIS RULE 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		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$ 0.00	Total	$ 0.00

   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	$ 0.00	Total	$ 0.00

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
$	$

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
$	$

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 Asa Hutchinson
José R. Romero, MD, Secretary of Health

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. Acetyl fentanyl, Valeryl fentanyl, Isobutyryl fentanyl, 4-methoxy butyryl fentanyl and Acetyl norfentanyl are opiates listed as Schedule I controlled substances. Page 2, (b), (59), (60), (62), (64) and (66). These items are marked for clean up. The salt designation is removed from the chemical nomenclature for these substances. References to salt formulations is currently documented in prefatory language for opiates in Schedule I. Page 2, (b), (59), (60), (62), (64) and (66).

2. Para-fluorobutyryl fentanyl is a Schedule 1 controlled substance. To follow DEA, a DEA Controlled Substance Code Number has been set forth opposite of this substance and is marked for clean up. The salt designation has also been removed from the chemical nomenclature for this substance as references to salt formulation is documented in the prefatory language for opiates in Schedule I Page 2, (b), (65)

3. Cyclopropyl fentanyl. N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide. 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, (b), (75).

4. Methoxyacetyl fentanyl. 2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide. 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, (b), (76).

5. Ortho-fluorofentanyl. N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide). 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, (b) (77).

6. Fentanyl-related substances, their isomers, esters, ethers, salts and salts of isomers, esters and ethers. Fentanyl-related substances means any substance not otherwise listed, and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355], that is structurally related to fentanyl by one or more of the following modifications:

   (A) Replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

   (B) Substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino or nitro groups;

   (C) Substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino or nitro groups;

   (D) Replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or

   (E) Replacement of the *N*-propionyl group by another acyl group.

   Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested this substance designation for fentanyl related substances with one or more of the following modifications and without a recognized medical use be included into Schedule I. Page 3, (b), (78).

7. Clonazolam. Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this depressant substance with no recognized medical use be included into Schedule I. Page 6, (e), (6).

8. Flualprazolam. Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this depressant substance with no recognized medical use be included into Schedule I. Page 6, (e), (7).

9. Flubromazepam. Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this depressant substance with no recognized medical use be included into Schedule I. Page 6, (e), (8).

10. Flubromazolam. Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this depressant substance with no recognized medical use be included into Schedule I. Page 6, (e), (9).

11. Ethylone. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one. The DEA has placed this synthetic cathinone into Schedule I because it has no recognized medical use. To follow DEA scheduling, this drug would be included as Schedule I. Page 7, (11), (b), (19).

12. Eutylone. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone. Felisia Lackey, Chief Forensic Chemist-drug Section, Arkansas State Crime Laboratory, requested this synthetic cathinone with no recognized medical use be included into Schedule I. Page 7, (11), (b), (20).

13. Noroxymorphone. The DEA placed this opioid analgesic into Schedule II. To follow DEA scheduling, this substance would be included as Schedule II. Page 8, (b), (1), (20).

14. Thiafentanil. The DEA placed this opioid analgesic into Schedule II. To follow DEA scheduling, this substance would be included as Schedule II. Page 9, (c), (28).

15. Norfentanyl. N-phenyl-N-(piperidin-4-yl)propionamide. The DEA has placed this immediate precursor to fentanyl into Schedule II. To follow DEA scheduling, this substance would be included as Schedule II. Page 10, (g), (3), (ii).

16. Brexanolone. The FDA approved this drug for the treatment of postpartum depression. To follow DEA, this drug would be included as Schedule IV. Page 16, (c), (57).

17. Lemborexant. The FDA approved this drug for the treatment of insomnia in adult patients. To follow DEA, this drug would be included as Schedule IV. Page 16, (c), (58).

18. Solriamfetol. The FDA approved this drug to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. To follow DEA, this drug would be included as a Schedule IV. Page 16, (e), (14).

19. Lasmiditan. The FDA approved this drug for the acute treatment of migraine with or without aura in adults. To follow DEA, this drug would be included as Schedule V. Page 18, (e), (4).

20. Cenobamate. The FDA approved this drug for the treatment of partial-onset seizures in adult patients. To follow DEA, this drug would be included as Schedule V. Page 18, (e), (5).

21. A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols. This drug is currently listed as a Schedule V substance. Page 18, (f), (1). To follow DEA this drug is removed from the controlled substance list.

22. The following synthetic cannabinoids are schedule VI controlled substances. To follow DEA, controlled substance code numbers have been set forth opposite the following substances:
    - 5F-AKB-48, Page 21, (I), (v),
    - 5-Fluoro-AMB, Page 22, (K), (xv),
    - 5-Fluoro-ADB, Page 22, (K), (xvii),
    - MDMB-CHMICA, Page 22, (K), (xix),
    - FUB-AMB, Page 22, (K), (xx),
    - MDMB-FUBINACA, Page 22, (K), (xxi).

23. Two items marked for clean-up:
    a. Page 22, (K), (xxiv)
    b. Page 22, (K), (xxvii).

24. ADB-FUBINACA. N-(1-amino-3,3-dimethyl-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 VI. Page 22, (K), (xxviii).

25. 4-Fluoro MDMB-BUTINACA. methyl (S)-2-(1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate. Felisia 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 23, (K), (xxix).