# EXHIBIT J

**DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION/PHARMACY SERVICES**

**SUBJECT: List of Controlled Substances in Arkansas**

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

1. Eluxadoline. The FDA approved this drug for treatment of irritable bowel syndrome with diarrhea. To follow DEA scheduling, this drug would be included as Schedule IV. Page 15, (f,4).

2. Brivaracetam. The FDA approved this drug for treatment of epilepsy. To follow DEA scheduling, this drug would be included as Schedule V. Page 16, (e,3).

3. Acetyl fentanyl. N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide. The DEA has placed this opioid analgesic into Schedule 1 because it has no recognized medical use. To follow DEA scheduling, this drug would be included as Schedule 1. Page 2, (56).

4. Butyryl fentanyl. N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide. The DEA has placed this opioid analgesic into Schedule 1 because it has no recognized medical use. To follow DEA scheduling, this drug would be included as Schedule 1. Page 2, (57).

5. Beta-hydroxythiofentanyl. N-{1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl}-N-phenylpropionamide. The DEA has placed this opioid analgesic into Schedule 1 because it has no recognized medical use. To follow DEA scheduling, this drug would be included as Schedule 1. Page 2, (58).

6. AH-7921. 3,4-dichloro-*N*-[(1dimethylamino) cyclohexylmethyl]benzamide. The DEA has placed this opioid analgesic into Schedule 1 because it has no recognized medical use in the United States. To follow the DEA scheduling, this drug would be included as Schedule 1. Page 2, (67).

7. W-18. 1-(4-nitrophenylethyl) piperidylidene-2-(4-chlorophenyl) sulfonamide. Page 2, (68). Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this dangerous synthetic opioid be included into Schedule 1. This drug is considered to be 100 times more potent than fentanyl and 10,000 times more potent than morphine.
More information regarding W-18 was obtained from Dr. Jeffery Moran with the ADH Public Health Lab, and for the following reasons, ADH Pharmacy Services recommends that W-18 be included into Schedule 1:
□ current scientific knowledge regarding emerging illicit drugs of concern
□ high potential for abuse and dependence
□ risk to the public health

The following drugs, similar to those listed above, will be included as Schedule 1:

8. Acetyl fentanyl 4-methylphenethyl analog. N-{1-[2-(4-methylphenyl)ethyl]-4-piperidinyl}-N-phenyl-acetamide monohydrochloride. Page 2, (59).

9. Valeryl fentanyl. N-phenyl-N[1-(2-phenylethyl)-4-piperidinyl]-pentanamide monohydrochloride. Page 2, (60).

10. Furanyl fentanyl. N-(1-(2-phenylethyl)-4-piperidinyl)-N-phenylfuran-2-carboxamide. Page 2, (61).

11. Isobutyryl fentanyl. 2-methyl-N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide monohydrochloride.Page 2, (62).

12. Octfentanil. N-(2-fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide. Page 2, (63).

13. 4-methoxy butyryl fentanyl. N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide monohydrochloride. Page 2, (64).

14. Para-flourobutyryl fentanyl. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide monohydrochloride. Page 2, (65).

15. Acetyl norfentanyl. N-phenyl-N-4-piperidinyl-acetamide monohydrochloride. Page 2, (66).

16. W-15. 1-phenylethylpiperidylidene-2-(4-chlorophenyl) sulfonamide. Page 2, (69).

17. MT-45. 1-cyclohexyl-4-(1,2-diphenylethyl) piperazine. Page 3, (70).

18. U-47700. trans-3,4-dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide. Page 3, (71).

**PUBLIC COMMENT:** A public hearing was held on September 26, 2016. The public comment period expired on September 26, 2016. The department received no comments.

The proposed effective date is March 1, 2017.

# EXHIBIT J

**CONTROVERSY:** This is not expected to be controversial.

**FINANCIAL IMPACT:** There is no financial impact.

**LEGAL AUTHORIZATION:** Arkansas Code Annotated § 20-7-109 (a)(1)(A) gives the Department of Health the authority to make all necessary and reasonable rules and regulations of a general nature for the protection of the public health and safety.

Specifically, Ark. Code Ann. § 5-64-201 (a)(1)(A)(i) states the Director of the Department of Health shall administer this chapter (Controlled Substances) and may add a substance to or delete or reschedule any substance enumerated in a schedule.

# QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE


**DEPARTMENT/AGENCY** Arkansas Department of Health

**DIVISION** Center for Health Protection/Pharmacy Services

**DIVISION DIRECTOR** Renee Mallory

**CONTACT PERSON** James Myatt

**ADDRESS** 4815 West Markham Street, Slot 25, 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** 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 in Arkansas

2. What is the subject of the proposed rule? Adding 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. Following the DEA scheduling in 6 of the scheduled drugs

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? This rule change updates the Controlled Substances List to include the following substances scheduled by the DEA: Eluxadoline; Brivaracetam; Acetyl fentanyl; Butyryl fentanyl; Beta-hydroxythiofentanyl; and AH-7921. It also adds W-18, pursuant to a request by the Crime Lab. W-18 is a dangerous synthetic opioid. The change also adds drugs similar to those specifically listed above.

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: September 26, 2016
Time: 1:00 PM
Place: Arkansas Dept of Health, Room L 137, 4815 West Markham, Little Rock, AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
12:00 PM, September 26, 2016

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
March 1, 2017

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 Crime Lab and Arkansas Law Enforcement Agencies -for
Others Unknown

## FINANCIAL IMPACT STATEMENT

### PLEASE ANSWER ALL QUESTIONS COMPLETELY

**DEPARTMENT** Arkansas Department of Health
**DIVISION** Center for Health Protection/Pharmacy Services
**PERSON COMPLETING THIS STATEMENT** Elizabeth Harris
**TELEPHONE NO.** 501-280-4034 **FAX NO.** 501-661-2357 **EMAIL:** sarah.harris@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 | _____ | General Revenue | _____ |
| Federal Funds | _____ | Federal Funds | _____ |
| Cash Funds | _____ | Cash Funds | _____ |
| Special Revenue | _____ | Special Revenue | _____ |
| Other (Identify) | _____ | Other (Identify) | _____ |

| | | | |
|---|---|---|---|
| Total | 0 | Total | 0 |

(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 | 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**
$ 0

**Next Fiscal Year**
$ 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**
$ 0

**Next Fiscal Year**
$ 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.