EXHIBIT G

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 Donnie Smith

CONTACT PERSON James Myatt, PD

ADDRESS 4815 West Markham, Slot 31, 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 James Myatt, PD

PRESENTER E-MAIL james.myatt@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
Room 315, State Capitol
Little Rock, AR 72201

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1. What is the short title of this rule? Rules and Regulations Pertaining to Controlled Substances

2. What is the subject of the proposed rule? Amending current regulations pursuant to Act 588 of 2011 and to be consistent with Arkansas State Board of Pharmacy and Drug Enforcement Administration changes

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 regulation.
The regulations are being amended to comply with Act 588 of 2011 and to incorporate changes to be consistent with Arkanas State Board of Pharmacy and Drug Enforcement Administration regulations.

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If yes, a copy of the repealed rule is to be included with your completed questionnaire.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 Arkansas Code citation.

Ark. Code Ann. § 5-64-201; Ark. Code Ann. § 20-7-109, Act 588 of 2011

7. What is the purpose of this proposed rule? Why is it necessary?
It is necessary to update the regulations to incorporate changes enacted in Act 588 of 2011 and to be consistent with Arkansas State Boardof Pharmacy and Drug Enforcement Administration changes.

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.healthy.arkansas.gov/aboutADH/Pages/RulesRegulationsProposed.aspx

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐

If yes, please complete the following:

Date: April 11, 2013

Time: 10:00 a.m.

Place: Arkansas Department of Health, Room 2508, 4815 West Markham, Little Rock, AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.) April 11, 2013

11. What is the proposed effective date of this proposed rule? (Must provide a date.) August 1, 2013

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 Board of Pharmacy, Arkansas State Board of Nursing, Arkansas Medical Board, Arkansas Medical Society, Arkansas Pharmacists Association, Arkansas Board of Dental Examiners, Arkansas Board of Optometry, Arkansas Podiatry Examining Board, Arkansas Veterinary Medical

Examining Board, Office of Prosecutor Coordinator, Arkansas Department of Human Services, Health Facility Services Arkansas Department of Health, Arkansas State Crime Laboratory, Drug Enforcement Admnistration

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Health

DIVISION Center for Health Protection, Pharmacy Services and Drug Control Branch

PERSON COMPLETING THIS STATEMENT James Myatt, PD

TELEPHONE NO. 501-661-2325 **FAX NO.** 501-661-2769 **EMAIL:** james.myatt@arkansas.gov

To comply with Act 1104 of 1995, 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 Controlled Substances

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☐ No ☒

2. Does this proposed, amended, or repealed rule affect small businesses? Yes ☐ No ☒
   If yes, please attach a copy of the economic impact statement required to be filed with the Arkansas Economic Development Commission under Arkansas Code § 25-15-301 et seq.

3. If you believe that the development of a financial impact statement is so speculative as to be cost prohibited, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please give the incremental cost for implementing the rule. Please indicate if the cost provided is the cost of the program.

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	NA	General Revenue	NA
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total		Total	

5. What is the total estimated cost by fiscal year to any party subject to the proposed, amended, or repealed rule? Identify the party subject to the proposed rule and explain how they are affected.

Current Fiscal Year	**Next Fiscal Year**
$ NA	$ NA

6. What is the total estimated cost by fiscal year to the agency to implement this rule? Is this the cost of the program or grant? Please explain.

Current Fiscal Year	**Next Fiscal Year**
$ NA	$ NA

ARKANSAS DEPARTMENT OF HEALTH
RULES AND REGULATIONS PERTAINING TO CONTROLLED SUBSTANCES
MARK UP JANUARY 2, 2013

SUMMARY OF PROPOSED CHANGES

The proposed revisions are necessary to comply with Act 588 of 2011 regarding handling of ephedrine, pseudoephedrine and phenylpropanolamine, to conform with Arkansas Board of Pharmacy regulations, and to incorporate DEA changes.

Act 588 was passed to clarify the role of pharmacists with regard to ephedrine, pseudoephedrine, or phenylpropanolamine, to improve the process for identifying persons authorized to purchase ephedrine, pseudoephedrine and phenylpropanolamine, and to authorize the Board of Pharmacy to propose additions to the list of drugs similar to ephedrine, pseudoephedrine and phenylpropanolamine.

The following changes are proposed:

Section II

The following changes are made to be consistent with the State Board of Pharmacy regulations and the intent of Act 588.

- A controlled substance listed in Schedule V which is not a prescription drug is determined by the Federal Food, Drug and Cosmetic Act, rather than the Arkansas Controlled Substance Act.
- Such substances may not be dispensed by a nonpharmacist employee even if under the supervision of a pharmacist.
- Record keeping must be in accordance with §21 CFR 1304.04.
- The item may be dispensed without a prescription unless one is required by any other Federal, State or Local law.

Per Act 588, unless dispensed under a prescription, all sales or transfers of ephedrine, pseudoephedrine and phenylpropanolamine are subject to quantity limits and restrictions:

- No more than three packages of products that contain ephedrine, pseudoephedrine and phenylpropanolamine in a single transaction;
- No more than a single package that contains more than 96 tablets, gelcaps, capsules, or other individual units or more than three grams in a single transaction;
- In a single transaction, any product containing ephedrine, pseudoephedrine, or phenylpropanolamine, unless:
    - package size is not more than three grams and is packaged in a blister pack with each blister containing not more than two dosage units;
    - when a blister pack is not feasible, is packaged in a unit dose packet or pouch; or
    - in the case of a liquid, the package size is not more than three grams.
- No product may be sold or transferred to any person under age 18, unless the person is purchasing an exempt product under Ark. Code Ann. § 5-64-1103 (b).
- No more than 5 grams of ephedrine or 9 grams of pseudoephedrine or phenylpropanolamine to a single patient in any 30 day period.
- The sale must be recorded in electronic format consistent with Board of Pharmacy regulations.

A driver's license or non-driver's identification card issued by Arkansas or an identification card issued by the Department of Defense to active duty military personnel that contains a photograph of the person, the person's date of birth and a functioning magnetic stripe or bar code is required to dispense, sell, or transfer ephedrine, pseudoephedrine and phenylpropanolamine in accordance with Act 588.

The federal law requirement which prohibits the sale of more than 3.6 grams of ephedrine, pseudoephedrine and phenylpropanolamine to a patient in any 24 hour period is included.

Section IV

Requirements for practitioners who discover suspected loss, theft and/or diversion are revised to be consistent with Board of Pharmacy regulations and DEA §21 CFR 1301.76 (b). Long-term care facilities must notify the Department Health.

Section VIII

Language is corrected to indicate the pharmacist's corresponding responsibility rather than liability (pages 12, 13) in conformance with DEA §21 CFR 1306.04 (a).

The prescriber of an oral prescription shall send a written prescription to the pharmacist within seven days of authorizing, rather than 72 hours (page 20), in conformance with DEA §21 CFR 1306.11 (d) (4).

In agreement with DEA §21 CFR 1306.12 (g), a prescription for a Schedule II substance for a hospice patient may be transmitted by facsimile (page 23).