EXHIBIT H

DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION

SUBJECT: Public Access to Auto-Injectable Epinephrine

DESCRIPTION: The proposed rules and regulation pertain to Act 1108 of 2015 as follows:

1. After training specified in this Act, a layperson may possess and administer auto-injectable epinephrine to a person who appears to be suffering a severe adverse allergic reaction.

2. Entities utilizing these laypersons are responsible for correct storage of this medication and for reporting to the Health Department each incident of usage of the medication. This reporting will be summarized and reported annually by the Health Department.

3. The Health Department will issue certificates to persons eligible to administer this medication and accept certificates issued pursuant to Section IV(3).

PUBLIC COMMENT: A public hearing was held on May 24, 2016. The public comment period expired on May 24, 2016. The Department received no comments.

The proposed effective date is August 15, 2016.

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: This rule implements Act 1108 of 2015. Arkansas Code Annotated § 20-7-109 (a)(1)(A) states that the State Board of Health has the authority to make all necessary and reasonable rules and regulations of a general nature for the protection of the public health and safety.

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 Renee Mallory

CONTACT PERSON James Myatt

ADDRESS 4815 West Markham St., Slot 25, Little Rock, Arkansas 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

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1. What is the short title of this rule? Rules and Regulations Pertaining to Public Access to Auto-Injectable Epinephrine

2. What is the subject of the proposed rule? Training of laypersons to possess and administer auto-injectable epinephrine to a person who appears to be suffering a severe adverse allergic reaction.

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. 1. After training specified in this Act, a layperson may possess and administer auto-injectable epinephrine to a person who appears to be suffering a severe adverse allergic reaction.
2. Entities utilizing these laypersons are responsible for correct storage of this medication and for reporting to the Health Department each incident of usage of the medication. This reporting will be summarized and reported annually by the Health Department.
3. The Health department will issue certificates to persons eligible to administer this medication and accept certificates issued purusant to Section IV(3).

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. Act 1108 of 2015, codified at Arkansas Code 20-13-403--408.

7. What is the purpose of this proposed rule? Why is it necessary? Required by Act 1108 of 2015.

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: May 24, 2016

Time: 10:00 AM

Place: Arkansas Department of Health, Room L137, 4815 West Markham, Little Rock, AR

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

12:00 PM, May 24, 2016

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

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.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health

DIVISION Center for Health Protection

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 Public Access to Auto-Injectable Epinephrine

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	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

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

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

PROPOSED RULES AND REGULATIONS PERTAINING TO PUBLIC ACCESS TO AUTO-INJECTABLE EPINEPHRINE

The proposed rules and regulations pertain to Act 1108 of 2015.

1. After training specified in this Act, a layperson may possess and administer auto-injectable epinephrine to a person who appears to be suffering a severe adverse allergic reaction.

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