

# EXHIBIT G

## DEPARTMENT OF HUMAN SERVICES, MEDICAL SERVICES

**SUBJECT:** Notice of Rule Making 005-15; Coverage of Vaccine Current Procedure Terminology (CPT) Procedure Codes 90620 and 90621

**DESCRIPTION:** To comply with the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control (CDC) recommendations that adolescents and young adults be vaccinated with the two MenB vaccines which were recently licensed by the Federal Food and Drug Administration (FDA). Both MenB vaccines were licensed based on statutory regulations for accelerated approval. This criterion was based on serious or life-threatening diseases based on safety and demonstration that the vaccines effectiveness will benefit children and young adults.

**PUBLIC COMMENT:** No public hearing was held. The public comment period expired on February 9, 2016. The Department received no comments.

The proposed effective date is April 1, 2016.

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

**FINANCIAL IMPACT:** The cost to implement this rule is \$87,100 (\$25,938 in general revenue and \$61,162 in federal funds) for the current fiscal year and \$87,100 (\$26,330 in general revenue and \$60,770 in federal funds) for the next fiscal year. The majority of the financial impact of this rule change is for the new vaccine coverage under the Vaccines for Children (VFC) and the State Children's Health Insurance Program (SCHIP) programs. A small portion of the impact is related to the new vaccines for the 19 to 25 population.

**LEGAL AUTHORIZATION:** Arkansas Code Annotated § 20-76-201 (12) gives the Department the general authority to "make rules and regulations and take actions as are necessary or desirable to carry out the provisions of this chapter and that are not inconsistent therewith."

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

DEPARTMENT/AGENCY Department of Human Services  
DIVISION Division of Medical Services  
DIVISION DIRECTOR Dawn Stehle  
CONTACT PERSON Cathy Coffman  
ADDRESS P.O. Box 1437, Slot S295, Little Rock, AR 72203-1437  
PHONE NO. 501-537-1670 FAX NO. (501)682-2480 E-MAIL cathy.coffman@dhs.arkansas.gov  
NAME OF PRESENTER AT COMMITTEE MEETING Tami Harlan  
PRESENTER E-MAIL tami.harlan@dhs.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, 5<sup>th</sup> Floor  
Little Rock, AR 72201**

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- 1. What is the short title of this rule? Notice of Rule Making Notice- Notice 005-15
  
- 2. What is the subject of the proposed rule? To inform providers of two new Meningococcal Vaccines and their appropriate Current Procedural Codes ( CPT)
  
- 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. \_\_\_\_\_

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. Arkansas Statute 20-76-201

7. What is the purpose of this proposed rule? Why is it necessary? The purpose of the proposed rule is to inform providers of coverage of the following CPT codes: 90620 and 90621 under the Vaccines for Children (VFC) and the State Children's Health Insurance Program (SCHIP). These two are new Meningococcal vaccines for children as recommended by the Centers for Disease Control and Prevention (CDC).

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).

<https://www.medicaid.state.ar.us/general/comment/comment.aspx>

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

If yes, please complete the following:

Date: \_\_\_\_\_

Time: \_\_\_\_\_

Place: \_\_\_\_\_

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

February 9, 2016

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

April 1, 2016

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.

Medical associations and interested providers are for this legislation.

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**FINANCIAL IMPACT STATEMENT**

**PLEASE ANSWER ALL QUESTIONS COMPLETELY**

**DEPARTMENT** Department of Human Services  
**DIVISION** Division of Medical Services  
**PERSON COMPLETING THIS STATEMENT** Brian Jones  
**TELEPHONE NO.** (501)537-2064 **FAX NO.** (501)682-2480 **EMAIL:** brian.jones@dhs.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** Notice of Rulemaking 005-15

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?

<u>Current Fiscal Year</u>		<u>Next Fiscal Year</u>	
General Revenue	<u>\$25,938</u>	General Revenue	<u>\$26,330</u>
Federal Funds	<u>\$61,162</u>	Federal Funds	<u>\$60,770</u>
Cash Funds	<u>                    </u>	Cash Funds	<u>                    </u>
Special Revenue	<u>                    </u>	Special Revenue	<u>                    </u>
Other (Identify)	<u>                    </u>	Other (Identify)	<u>                    </u>

Total \$87,100

Total \$87,100

(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**

**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**

\$ \$25,9380

\$ \$26,330

The majority of the financial impact of this rule change is for the new vaccine coverage under the Vaccines for Children (VFC) and the State Children's Health Insurance Program (SCHIP) programs. A small portion of the impact is related to the new vaccines for 19 to 25 population.

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.

### **Summary for Notice 005-15 - Coverage for 90620 and 90621**

In order to comply with Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) recommendations that adolescents and young adults be vaccinated with the two MenB vaccines which were recently licensed by the Federal Food and Drug Administration (FDA). Both MenB vaccines were licensed based on statutory regulations for accelerated approval. This criterion was based on serious or life-threatening diseases based on safety and demonstration that the vaccines effectiveness will benefit children and young adults. This is filed emergent due to imminent peril to public health, welfare and safety of Arkansas Medicaid beneficiaries. Arkansas Medicaid must wait for all recommending bodies (i.e. CDC, ACIP and FDA) to concur before implementation and once release is determined; it must be filed emergent in order to address the timely safety and well-being of the Arkansas Medicaid beneficiaries and the Vaccines for Children participants.