EXHIBIT J

DEPARTMENT OF HUMAN SERVICES, MEDICAL SERVICES

SUBJECT: State Plan Amendment #2018-012: Include Managed Care Organizations in the State Supplemental Rebate Program

DESCRIPTION: Effective January 1, 2019, the state supplemental rebate agreements will apply to the drug benefit, both fee-for-service and those paid by contracted managed care organizations (MCO), under prescribed conditions of the State of Arkansas Supplemental Rebate Agreement. State supplemental rebate agreements will apply to beneficiaries receiving fee-for-service benefits under the Affordable Care Act that are assigned to MCOs. This change is to allow the State to collect supplemental rebates from manufacturers for encounter data for claims paid under the MCO's plans.

PUBLIC COMMENT: DHS held three public hearings, one in Little Rock on August 20, 2018, one in Monticello on September 4, 2018, and one in Hope on September 6, 2018. The public comment period ended on September 12, 2018. DHS received no comments.

DHS has sought approval from CMS, and formal approval is pending.

The proposed effective date of the rule is January 1, 2019.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: DHS is authorized to "make rules and regulations and take actions as are necessary or desirable to carry out the provisions of this chapter [Public Assistance] and that are not inconsistent therewith." Arkansas Code Annotated § 20-76-201(12). DHS may promulgate rules as necessary to conform to federal rules that affect its programs as necessary to receive any federal funds. *See* Ark. Code Ann. § 25-10-129(b).

Exhibit J

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Department of Human Services

DIVISION Division of Medical Services

INTERIM DIVISION DIRECTOR Tami Harlan

CONTACT PERSON Jason Derden

ADDRESS PO Box 1437, Slot S415, Little Rock, AR 72203-1437

PHONE NO. 501-320-6178 **FAX NO.** 501-404-4619 **E-MAIL** jason.derden@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, 5th Floor
Little Rock, AR 72201

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1. What is the short title of this rule? State Plan Amendment #2018-012

2. What is the subject of the proposed rule? To include Managed Care Organizations (MCO) in the State Supplemental Rebate Program

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? N/A
   When does the emergency rule expire? N/A
   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."** This change is to allow the State to collect Supplemental Rebates from manufacturers for encounter data for claims paid under the MCO plans.

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? Without this SPA change the State will not be able to collect State Supplemental rebate on claims paid by the MCOs

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://medicaid.mmis.arkansas.gov/general/comment/comment.aspx

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

Date: August 20, 2018; September 6, 2018

Time: 5:00 PM

Place: Central Library, Darragh Auditorium,
100 Rock Street
Little Rock, AR

Hempstead Hall, Blevins Suite,
University of Arkansas at Hope
2500 South Main Street
Hope, AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
September 12, 2018

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
January 1, 2019

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. See attached.

13. Please provide proof of filing the rule with the Secretary of State and the Arkansas State Library as required pursuant to Ark. Code Ann. § 25-15-204(e). See attached.

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. Do not expect any positions for or against this rule.

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 501-537-2064 **FAX** 501-382-3889 **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 State Plan Amendment #2018-012

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		Total	

(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		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
$ $0

Next Fiscal Year
$ $0

Budget Neutral as already receiving rebate on these claims, will continue as Beneficiaries move to PASSE.

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 STATE PLAN AMENDMENT #2018-012

Effective January 1, 2019, the state supplemental rebate agreements will apply to the drug benefit, both fee-for-service and those paid by contracted managed care organizations (MCO), under prescribed conditions of the State of Arkansas Supplemental Rebate Agreement. State Supplemental rebate agreements will apply to beneficiaries receiving fee-for-service benefits under the Affordable Care Act that are assigned to MCOs. This change is to allow the State to collect Supplemental Rebates from manufacturers for encounter data for claims paid under the MCO's plans.

Mark up

12. Prescribed drugs, dentures and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist (Continued)

a. Prescribed Drugs (continued)

(4) The state is in compliance with section 1927 of the Social Security Act. The state will cover drugs of Federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data.

The state will be negotiating supplemental rebates in the Medicaid program in addition to the Federal rebates provided for in Title XIX. Rebate agreements between the state and pharmaceutical manufacturer(s) will be separate from the Federal rebates.

A rebate agreement between the state and a participating drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on May 24, 2016, and entitled, State of Arkansas Supplemental Rebate Agreement, has been authorized by CMS. Any additional versions of rebate agreements negotiated between the state and manufacturer(s) after May 24, 2016, will be submitted to CMS for authorization.

The state supplemental rebate agreements would apply to the drug benefit, both fee-for-service and those paid by contracted Medicaid managed care organizations (MCOs), under prescribed conditions in Attachment C of the State of Arkansas Supplemental Rebate Agreement. State supplemental rebate agreements would apply to beneficiaries, including those made eligible under the Affordable Care Act receiving fee-for-service benefits and those that are enrolled under a Medicaid managed care organization agreement.

Supplemental rebates received by the State in excess of those required under the National Drug Rebate Agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provisions of the national drug rebate agreement.

The supplemental rebate program does not establish a drug formulary within the meaning of 1927(d)(4) of the Social Security Act.

The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification, in accordance with Section 1927(b)(3)(D) of the Social Security Act.

(5) Pursuant to 42 U.S.C. Section 1396r-8 the state is establishing a preferred drug list with prior authorization for drugs not included on the preferred drug list. Prior authorization will be provided within a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in emergency situations.

MEDICALLY NEEDY

12. Prescribed drugs, dentures and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist (Continued)

a. Prescribed Drugs (continued)

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