DEPARTMENT OF HUMAN SERVICES, MEDICAL SERVICES

SUBJECT: State Plan #2016-002 and Supplemental Rebate Agreement

DESCRIPTION: The Arkansas Medicaid State Supplemental Rebate Program along with the State Supplemental Rebate Agreement (SSRA) was approved by CMS in the State Plan Amendment (SPA 04-04) with an effective date of October 15, 2004. The State Plan Amendment indicated that any additional versions of the State Supplemental Rebate Agreement negotiated between the state and manufacturer(s) after November 16, 2004 would need to be submitted to CMS for authorization. Arkansas's State Supplemental Rebate Agreement has not changed since the initial approval which uses the state's pharmacy reimbursement methodology to calculate State Supplemental Rebate Payment by manufacturers. Due to the final Outpatient Drug Rule moving to a reimbursement model based on actual acquisition cost, Arkansas Medicaid is revising the SSRA to transition to the more standard WAC based State Supplemental Rebate Payment calculation. In addition, Arkansas Medicaid is updating the entire SSRA to include additional definitions and process consistent with other Medicaid State's SSRAs in which Magellan Medicaid Administration has standings.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on September 6, 2016. The department received no comments.

The proposed effective date is November 1, 2106.

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: The Department of Human Services 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).

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

DF	EPARTMENT/AGENCY	Department of Human Services					
DI	VISION	Division of Medical Services					
DI	VISION DIRECTOR	Dawn Stehle					
	ONTACT PERSON ODRESS	Thomas Herndon PO Box 1437, Slot S295, Little Rock, AR 72203					
	IONE NO. 501-396-60	thomas.herndon@					
		FAX NO. 501-404-4619 E-MAIL dhs.arkansas.gov COMMITTEE MEETING Tami Harlan					
		mi.harlan@dhs.arkansas.gov					
		mi.markarty.dns.artxansass.gov					
		INSTRUCTIONS					
	of this Rule" below. Submit two (2) copies of to of two (2) copies of the pr Donna K. Dav Administrative Arkansas Legi	e Rules Review Section islative Council pislative Research Mall, 5 th Floor					
**	*********	*******************					
1.	What is the short title of th	is rule? State Plan #2016-002 and Supplemental Rebate Agreement					
2.	What is the subject of the p	proposed rule? Updating the Supplemental Rebate Agreement					
3.		ply with a federal statute, rule, or regulation? Yes No ederal rule, regulation, and/or statute citation.					
4.	Procedure Act?	ne emergency provisions of the Administrative Yes \(\subseteq \text{No } \subseteq \)					
	If yes, what is the effective	e date of the emergency rule?					
	When does the emergency	rule evnire?					

	Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes No					
5.	s this a new rule? Yes No No No state of yes, please provide a brief summary explaining the regulation.					
	Does this repeal an existing rule? Yes No No 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 In 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. <u>Arkansas Statute 20-76-201</u>					
7. What is the purpose of this proposed rule? Why is it necessary? The Arkansas Medicaid State Supplemental Rebate Program along with the State Supplemental Rebate Agreement (SSRA) was approved by CMS in the State Plan Amendment (SPA 04-04) with an effective date of October 15, 2004. The State Plan Amendment indicated that any additional versions of the State Supplemental Rebate Agreement negotiated between the State and manufacturer(s) after November 16, 2004 would need to be submitted to CMS for authorization. Arkansas's State Supplemental Rebate Agreement has not changed since the initial approval which uses the State's pharmacy reimbursement methodology to calculate State Supplemental Rebate Payment by manufacturers. Due to the final Outpatient Drug Rule moving to a reimbursement model based on actual acquisition cost Arkansas Medicaid is revising the SSRA to transition to the more standard WAC based State Supplemental Rebate Payment calculation. In addition, Arkansas Medicaid is updating the entire SSRA to include additional definitions and a process consistent with other Medicaid State's SSRAs in which Magellan Medicaid Administration has standings.						
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 No If yes, please complete the following: Date: Time: Place:					
	. When does the public comment period expire for permanent promulgation? (Must provide a date.) eptember 6, 2016					

11. What is the proposed effective date of this proposed rule? (Must provide a date.) November 1, 2016						
12. Do you expect this rule to be controversial? Yes \(\scale= \) No \(\scale= \) 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			Department of Human Services						
DIVISION			Division of Medical Services						
PEF	RSON	COMPLE	TING THIS ST	TATEMENT Bri	an Jones				
TELEPHONE NO. 501-537-2064 FAX NO. 501-404-4619 EMAIL: brian.jones@dhs.arkansas.gov									
To Sta	comp temen	ly with Ark. t and file tw	Code Ann. § 25 to copies with the	5-15-204(e), pleas e questionnaire a	e complete the following proposed rules.	g Financial	mpact		
SHORT TITLE OF THIS RULE State Plan #2016-002 & Supplemental Rebate Agreement									
1. Does this proposed, amended, or repealed rule have a financial impact? Y					Yes 🗌	No 🖂			
2.	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 ■						No 🗌		
3.	3. In consideration of the alternatives to this rule, was this 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, an if so, please explain; and;					welfare, and			
	(d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.						so, please		
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?					wing:				
	Current Fiscal Year			Next Fiscal Year					
	General Revenue Federal Funds Cash Funds Special Revenue Other (Identify)			General Revenue Federal Funds Cash Funds Special Revenue Other (Identify)					

Total		Total	_1.00_0		
(b) What is the ac	dditional cost of the s	tate rule?			
Current Fiscal	<u>Year</u>	Next Fiscal Year			
General Revenue Federal Funds Cash Funds Special Revenue	\$0	Special Revenue	\$0 \$0		
Other (Identify) Total	\$0	Total	\$0		
 What is the total exproposed, amended they are affected. Current Fiscal Year	ed, or repealed rule?	al year to any private individual, entity identify the entity(ies) subject to the part Fiscal	proposed rule and explain how		
\$	-	\$			
rule? Is this the cost of the program or grant. Current Fiscal Year \$ \$0			Next Fiscal Year		
Date changes to the	- state plan have no fin	ancial impact.			
or obligation of a private entity, pr	at least one hundred the	to Questions #5 and #6 above, is there housand dollars (\$100,000) per year to government, county government, mundined?	o a private individual,		
		Yes ☐ No ⊠			
, .	e written findings at the filed simultaneously are following:				
(1) a statement of	of the rule's basis and	purpose;			
	the agency seeks to a nired by statute;	ddress with the proposed rule, includi	ing a statement of whether		
(3) a description	of the factual eviden	ce 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 #2016-002 AND SUPPLEMENTAL REBATE AGREEMENT

The Arkansas Medicaid State Supplemental Rebate Program along with the State Supplemental Rebate Agreement (SSRA) was approved by CMS in the State Plan Amendment (SPA 04-04) with an effective date of October 15, 2004. The State Plan Amendment indicated that any additional versions of the State Supplemental Rebate Agreement negotiated between the State and manufacturer(s) after November 16, 2004 would need to be submitted to CMS for authorization. Arkansas's State Supplemental Rebate Agreement has not changed since the initial approval which uses the State's pharmacy reimbursement methodology to calculate State Supplemental Rebate Payment by manufacturers. Due to the final Outpatient Drug Rule moving to a reimbursement model based on actual acquisition cost Arkansas Medicaid is revising the SSRA to transition to the more standard WAC based State Supplemental Rebate Payment calculation. In addition, Arkansas Medicaid is updating the entire SSRA to include additional definitions and a process consistent with other Medicaid State's SSRAs in which Magellan Medicaid Administration has standings.