ARKANSAS REGISTER

Proposed Rule Cover Sheet

Secretary of State
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Name of Department Department of Human Services

Agency or Division Name Division of Medical Services

Other Subdivision or Department, If Applicable

Previous Agency Name, If Applicable

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Name of Rule Preferred Drug List Pool and Value-Based Purchasing

Newspaper Name Arkansas Democrat Gazette

Date of Publishing January 23, 2022

Final Date for Public Comment February 21, 2022

Location and Time of Public Meeting February 15, 2022 at 2 p.m. via Zoom at https://us02web.zoom.us/j/89719467161, webinar id 897 1946 7161

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

Revised: ~~January 1, 2019~~May 1, 2022

CATEGORICALLY 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)

(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.

Effective May 1, 2022, the state may join a Preferred Drug List (PDL) pool to maximize state supplemental rebates. The state will continue to select products participating in the Federal rebate program that will be in its Preferred Drug List Program and will only receive state supplemental rebates for manufacturer's supplemental covered products included on the PDL.

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 state may enter into value-based contracts with manufacturers on a voluntary basis effective May 1, 2022~~1~~. These contracts will be executed on the model agreement entitled "Value-Based Supplemental Rebate Agreement". The state may enter into outcome-based contracts with manufacturers on a voluntary basis effective May 1, 2022~~1~~. The conditions of the outcome-based contract would be agreed upon by both the state and manufacturer.

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.

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

Revised: ~~January~~ May 1, ~~2019~~2022

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)

(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.

Effective 5/1/2022, the state may join a Preferred Drug List (PDL) pool to maximize state supplemental rebates. The state will continue to select products participating in the Federal rebate program that will be in its Preferred Drug List Program and will only receive state supplemental rebates for manufacturer's supplemental covered products included on the PDL.

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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 state may enter into value-based contracts with manufacturers on a voluntary basis effective May 1, 2022. These contracts will be executed on the model agreement entitled "Value-Based Supplemental Rebate Agreement". The state may enter into outcome-based contracts with manufacturers on a voluntary basis effective May 1, 2022. The conditions of the outcome-based contract would be agreed upon by both the state and manufacturer.

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.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Human Services
DIVISION Division of Medical Services
PERSON COMPLETING THIS STATEMENT Lynn Burton
TELEPHONE NO. 501-682-1857 **FAX NO.** _____ **EMAIL:** Lynn.Burton@dhs.arkansas.go

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 Preferred Drug List Pool and Value-Based Purchasing

1. Does this proposed, amended, or repealed rule have a financial impact?
   Yes ____X____ 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_____X_____ 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_____X_____ 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;

   N/A

   (b) The reason for adoption of the more costly rule;

   N/A

   (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and

   N/A

   (d) Whether the reason is within the scope of the agency's statutory authority, and if so, please explain.

   N/A

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	(522,683)	General Revenue	(570,200)
Federal Funds	(1,310,650)	Federal Funds	(1,429,800)
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	(1,833,333)	Total	(2,000,000)

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**
$ (1,833,333)	$ (2,000,000)

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__X__

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;

N/A

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

N/A

(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;

N/A

(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;

N/A

(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

N/A

(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.

N/A

Statement of Necessity and Rule Summary
Preferred Drug List (PDL) Pool and Value-Based Purchasing (VBP)

Why is this change necessary? Please provide the circumstances that necessitate the change.

Given the rising cost of pharmaceuticals in America and specifically in the Arkansas Medicaid Program, DMS is looking for innovative ways to decrease costs of the program while still providing Medicaid beneficiaries with quality care and access to drugs.

Working with a Preferred Drug List (PDL) pool allows for higher supplemental rebates from the manufacturers, due to "buying power" as more states participate. The state estimates a savings of two million dollars ($2,000,000) per year by joining a PDL pool, versus remaining an independent state in rebate negotiations.

Additionally, Value-Based Purchasing (VBP) allows for discount agreements with manufacturers on high-cost medications that can be tied to patient outcomes. Value-based and outcomes-based purchasing agreements are recommended by our federal partners as ways to realize savings and promote quality of care.

1. Currently, Arkansas is in contract with Magellan to negotiate state supplemental rebates for many drug classes on the Preferred Drug List (PDL). Manufacturers give us state supplemental rebates (which are in addition to federal rebates required by CMS) on medications, to ensure their product is preferred within our plan. Arkansas acts as an independent state when it comes to negotiations. Arkansas Medicaid "owns" the rebate contracts. Magellan is responsible for obtaining bids for supplemental rebates, monitoring the rebate contracts, and the upkeep of the PDL. The Drug Review Committee reviews the PDL drug classes for safety and efficacy while the Drug Cost Committee reviews the rebate bids and overall net cost to the state. Both committee recommendations are considered when deciding the preferred drug list. Ultimately, the Medicaid program decides which drug classes will be on the PDL, which rebate bids will be accepted, and which products will be listed as preferred or nonpreferred. By joining a PDL pool, the influence of multiple states in the pool drives the supplemental rebates received.

2. Value-Based Purchasing (VBP) is a rather new concept first started by Oklahoma. VBP allows Medicaid programs to contract directly with manufacturers (outside of PDL) for discounts/rebates. Arkansas will use a template contract that CMS approved previously for other states when entering VBP agreements. Basically, there are 2 methods of negotiations with manufacturers.
   A) VBP can be used as a discount only with negotiated agreements around approval of the drug (these high-priced drugs usually require prior authorizations).
   B) VBP can be tied to patient outcome. Example: A contract might state that if the patient has no response or dies while on this medication or within a certain timeframe, the manufacturer will refund some of the cost (usually a prorated amount depending on length of time since approval).

What is the change? Please provide a summary of the change.

Provision 1: DMS adds that the state may join a PDL pool to maximize state supplemental rebates. The state will continue to select products participating in the Federal rebate program that will be in its PDL Program and will only receive state supplemental rebates for manufacturer's supplemental covered products included on the PDL list.

Provision 2: DMS adds that the state may enter value-based contracts with manufacturers on a voluntary basis. These contracts will be executed on the model agreement entitled "Value-Based Supplemental Rebate Agreement". The state may enter into outcome-based contracts with manufacturers on a voluntary basis, the conditions of which would be agreed upon by both the state and the manufacturer.

The state estimates an annual savings of $2,000,000, of which $570,200 is state general revenue.

Please attach additional documents if necessary

NOTICE OF RULE MAKING

The Director of the Division of Medical Services of the Department of Human Services announces for a public comment period of thirty (30) calendar days a notice of rulemaking for the following proposed rule under one or more of the following chapters, subchapters, or sections of the Arkansas Code: §§ 20-76-201, 20-77-107, and 25-10-129.

Effective May 1, 2022:

The Director of the Division of Medical Services (DMS) is adding two provisions to the Arkansas State Medicaid Plan concerning prescription drugs. The provisions involve Preferred Drug Lists (PDL) and Value Based Purchasing (VBP). DMS is making these changes to combat the rising cost of pharmaceuticals while still providing Medicaid beneficiaries with quality care and access to medications. Working with a PDL allows for higher supplemental rebates from the manufacturer, due to buying power as more states participate. VBP allows for discount agreements directly with manufacturers on high cost medications outside of the PDL.

Provision 1: DMS adds that the state may join a PDL pool to maximize state supplemental rebates. The state will continue to select products participating in the Federal rebate program that will be in its PDL Program and will only receive state supplemental rebates for manufacturer's supplemental covered products included on the PDL list.

Provision 2: DMS adds that the state may enter value-based contracts with manufacturers on a voluntary basis. These contracts will be executed on the model agreement entitled "Value-Based Supplemental Rebate Agreement". The state may enter into outcome-based contracts with manufacturers on a voluntary basis, the conditions of which would be agreed upon by both the state and the manufacturer.

The state estimates an annual savings of $2,000,000, of which $570,200 is state general revenue.

The proposed rule is available for review at the Department of Human Services (DHS) Office of Rules Promulgation, 2nd floor Donaghey Plaza South Building, 7th and Main Streets, P. O. Box 1437, Slot S295, Little Rock, Arkansas 72203-1437. You may also access and download the proposed rule at https://humanservices.arkansas.gov/do-business-with-dhs/proposed -rules/. Public comments must be submitted in writing at the above address or at the following email address: ORP@dhs.arkansas.gov. All public comments must be received by DHS no later than February 21, 2022. Please note that public comments submitted in response to this notice are considered public documents. A public comment, including the commenter's name and any personal information contained within the public comment, will be made publicly available and may be seen by various people.

A public hearing by remote access only will be held on February 15, 2022 at 2:00 p.m. Individuals can access this public hearing by calling 1-888-240-3210 and entering the conference code, **897 1946 7161**.

If you need this material in a different format, such as large print, contact the Office of Rules Promulgation at 501-396-6428.

The Arkansas Department of Human Services is in compliance with Titles VI and VII of the Civil Rights Act and is operated, managed and delivers services without regard to religion, disability, political affiliation, veteran status, age, race, color or national origin. 4502035775

Elizabeth Pitman, Director
Division of Medical Services