ARKANSAS REGISTER

Transmittal Sheet

Use only for **FINAL** and **EMERGENCY RULES**

Secretary of State
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For Office Use Only:

Effective Date _____ Code Number _____

Name of Agency Department of Human Services

Department Division of Medical Services

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Statutory Authority for Promulgating Rules Arkansas Code Annotated 20-76-201

Rule Title: State Plan Amendment # 2016-003 Pharmacy Pricing Methodology

Intended Effective Date (Check One)

- ☐ Emergency (ACA 25-15-204)
- ☑ 10 Days After Filing (ACA 25-15-204)
- ☐ Other _____ (Must be more than 10 days after filing date.)

	Date
Legal Notice Published	12/01/2016
Final Date for Public Comment	12/30/2016
Reviewed by Legislative Council	06/16/2017
Adopted by State Agency	04/01/2017

Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218)

Thomas Herndon (Contact Person) thomas.herndon@dhs.arkansas.gov (E-mail Address) _____ (Date)

CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted
In Compliance with the Arkansas Administrative Act. (ACA 25-15-201 et. seq.)

Dawn Stehle /DH
Signature

(501) 683-4997 (Phone Number) dawn.stehle@dhs.arkansas.gov (E-mail Address)

Director
Title

6/20/17
Date

Revised 7/2015 to reflect new legislation passed in the 2015 Regular Session (Act 1258). This act changed the effective date from 30 days to 10 days after filing the 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 NO. 501-537-2064 **FAX NO.** 501-682-3889 **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 #2016-003 – Pharmacy Pricing Methodology

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 Does this proposed, amended, or repealed rule have a financial impact?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	$ (1,567,653)	General Revenue	$ (6,119,360)
Federal Funds	$ (3,618,100)	Federal Funds	$ (14,680,640)
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	

Total $ (5,185,753) Total $ (20,800,000)

(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		Total	

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
$ (3,118,079)

Next Fiscal Year
$ (6,306,560)

There is an estimated annual 42.6 million dollar ingredient savings and an estimated annual increase in the dispensing fee of 21.8 million for a net savings of 20.8 million in State and Federal dollars due to change in methodology.

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.

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

a. Prescribed Drugs

A. Payment for ingredient cost for covered outpatient legend and non-legend drugs for all pharmacy and medication types that are not otherwise identified within this section shall be based upon the lesser of methodology.

Lesser of Methodology:

i. Brand Drugs

a. The usual and customary charge to the public or submitted ingredient cost;

OR

b. The National Average Drug Acquisition Cost (NADAC) plus the established professional dispensing fee;

OR

c. The ACA Federal Upper Limit (FUL) plus the established professional dispensing fee;

OR

d. The calculated State Actual Acquisition Cost (SAAC), as defined in B, plus the established professional dispensing fee

ii. Generic Drugs

a. The usual and customary charge to the public or submitted ingredient cost;

OR

b. The National Average Drug Acquisition Cost (NADAC) plus the established professional dispensing fee;

OR

c. The ACA Federal Upper Limit (FUL) plus the established professional dispensing fee;

OR

d. The calculated State Actual Acquisition Cost (SAAC), as defined in B, plus the established professional dispensing fee

iii. Backup Ingredient Cost Benchmark

If NADAC is not available, the allowed ingredient cost, unless otherwise defined, shall be the lesser of Wholesale Acquisition Cost (WAC) + 0%, State Actual Acquisition Cost (SAAC) or ACA Federal Upper Limit.

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

a. Prescribed Drugs (Continued)

iv. Limited Access and Specialty Drugs

Limited Access Drugs, defined as drugs not available for dispensing in all retail pharmacies based on price or separate agreements between manufacturer and pharmacy, and Specialty Drugs will be reimbursed at the Lesser of Methodology plus the established professional dispensing fee. If NADAC is not available then the Backup Ingredient Cost Benchmark will apply which will use the lesser of Wholesale Acquisition Cost (WAC) + 0% or State Actual Acquisition Cost (SAAC).

v. 340B Drug Pricing Program

a. Covered Legend and non-legend drugs, including specialty drugs, purchased through the Federal Public Health Service's 340B Drug Pricing Program (340B) by pharmacies that carve Medicaid into the 340B Drug Pricing Program shall be reimbursed at the 340B actual Invoice Price but no more than the 340B ceiling price [provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)] plus the established professional dispensing fee. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered.

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b. Physician administered drugs, including specialty drugs, purchased through the 340B Program will be reimbursed at the 340B actual invoice price but no more than the 340B ceiling price [provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)].

vi. Federal Supply Schedule (FSS) and FQHC

Facilities purchasing drugs, specialty drugs, and physician administered drugs through the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. 1826, 42 U.S.C. 256b, or 42 U.S.C. 1396-8, other than the 340B Drug Pricing Program, shall be reimbursed no more than the Federal Supply Schedule price. The addition of the established professional dispensing fee for pharmacies will apply except in the cases of physician administered drugs. Federally Qualified Health Centers (FQHC) that purchase drugs through the 340B program and carve in Medicaid will be reimbursed by the encounter rate except in the case of Implantable Contraceptive Capsules, Intrauterine Devices, and Contraceptive Injections in which case reimbursement will be no more than the 340B ceiling price. Federally Qualified Health Centers (FQHC) that do not participate in the 340B program or carve out Medicaid will be reimbursed by the encounter rate except in the case of Implantable Contraceptive Capsules, Intrauterine Devices, and Contraceptive Injections in which case reimbursement will be at the actual acquisition cost.

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

a. Prescribed Drugs (Continued)

vii. Clotting Factor

a. Pharmacies dispensing Antihemophilic Factor products will be reimbursed at the lesser of methodology plus the established professional dispensing fee. The lesser of methodology for the allowed ingredient cost shall be the Wholesale Acquisition Cost (WAC) + 0% or State Actual Acquisition Cost (SAAC).

b. Pharmacies dispensing Antihemophilic Factor products purchased through the Federal Public Health Service's 340B Drug Pricing Program (340B) by pharmacies that carve Medicaid into the 340B Drug Pricing Program shall be reimbursed at the lesser of methodology plus the established professional dispensing fee. The lesser of methodology for the allowed ingredient cost shall be the Wholesale Acquisition Cost (WAC) + 0% or State Actual Acquisition Cost (SAAC).

viii. Drugs Purchased at Nominal Price

Facilities purchasing drugs at Nominal Price (outside of 340B or FSS) shall be reimbursed by their actual acquisition cost.

ix. Physician Administered Drugs

Reimbursement rates for Physician Administered Drugs are a "fee schedule" as determined by the Medicare rate (ASP + 6%). If the Medicare rate is not available then other published pricing or manual pricing shall be used to determine reimbursement. Under the fee schedule methodology, reimbursement is based on the lesser of the billed charge for each procedure or the maximum allowable for each procedure.

B. State Upper Limit (SUL) shall apply to certain drugs identified administratively, judicially or by a federal agency as having a published price exceeding the ingredient cost. The calculated SAAC shall be obtained from actual acquisition costs from multiple resources, if available. Depending on the variance, either the highest acquisition cost, an average of the acquisition costs or invoice price shall be used in determining a SAAC. When Brand and Generic drugs are available for the same ingredient, reimbursement will be based on the Generic State Actual Acquisition Cost (SAAC).

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

a. Prescribed Drugs (Continued)

C. Investigational drugs are excluded from coverage.

D. The State does not have federally recognized tribes. Indian Health Services, tribal and urban Indian pharmacies payment methodology for outpatient administered medication does not apply.

E. Pharmacies providing covered outpatient prescription services for Certified Long-Term Care beneficiaries will be reimbursed for ingredient cost using the lesser of methodology plus the established professional dispensing fee.

F. The Professional Dispensing Fee for covered outpatient legend and non-legend drugs shall take into consideration the State's Preferred Drug List status for the drug being dispensed and equals the average professional dispensing fee in the aggregate:

- **Brand and Non-preferred Brand = $9.00**
- **Brand Preferred and Generic Medication drug = $10.50**

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