## FINANCIAL IMPACT STATEMENT

# PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT	Department of Human Services			
DIVISION	IVISION Division of Medical Services			
PERSON COMPLE	TING THIS STATEMENT Lynn Burton			
TELEPHONE NO. 501-682-1857 FAX NO. 501-404-4619 EMAIL: lynn.burton@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 Pharmacy #3-15				
1. Does this propose	ed, amended, or repealed rule have a financial impact? Yes $\Box$ No $\boxtimes$			
2 Is the rule based	on the best reasonably obtainable scientific, technical,			

2.	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?

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

Yes 🕅

No 🗌

\$0	General Revenue	\$0
\$0	Federal Funds	\$0
	Cash Funds	
	Special Revenue	
	Other (Identify)	
		\$0 Federal Funds Cash Funds Special Revenue

Total	\$0	Total	\$0	
b) What is the addit	ional cost of the state rule?			
Current Fiscal Yea	<u>r</u>	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		

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total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule?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
\$ 0	\$ 0
This cost avoidance/savings was included in State Plan Amendme	nt 2016-003 – Pharmacy Pricing
Methodology. This is just the change to the manuals reflecting that	at change in methodology. Changing the
manuals has no additional impact.	

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?

IES   NO	Yes		No	X
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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 Pharmacy 1-17 & Section 1 1-17

CMS published the Covered Outpatient Drug final rule (CMS-2345-FC) (81 FR 5170) on 02/01/2016, pertaining to reimbursement for covered outpatient drugs in the Medicaid program. It outlines key changes that States need to address when determining their reimbursement methodology for ingredient costs based on actual acquisition cost (AAC) plus a professional dispensing fee among other things.



**Division of Medical Services** 

**Program Development & Quality Assurance** 

P.O. Box 1437, Slot S295 · Little Rock, AR 72203-1437 501-320-6428 · Fax: 501-404-4619 TDD/TTY: 501-682-6789



TO:	Arkansas Medicaid H	lealth Care Providers	- Pharmacy
EFFECTIVE DATE:	April 1, 2017		
SUBJECT:	Provider Manual Upd	ate Transmittal PHA	RMACY-1-17
REMOVE		INSERT	
Section 211.000	Effective Date 11-1-15	Section 211.000	Effective Date 4-1-17
217.000	10-1-16	217.000	4-1-17
219.000	3-14-15	219.000	4-1-17
251.000	4-1-07	251.000	4-1-17
251.200	11 <mark>-15-</mark> 11	251.200	4-1-17
251.300	3-14-15		
251.301	3-14-15		

## **Explanation of Updates**

Section 211.000 is updated with new program coverage information.

Section 217.000 is updated with information regarding the Federal Public Health Service's 340B Drug Pricing Program.

Section 219.000 is updated with new information regarding the use of generic drugs.

Section 251.000 is updated with new reimbursement methodologies.

Section 251.200 is updated to remove information regarding Estimated Acquisition Cost and to include information regarding Brand Medically Necessary Override.

Section 251.300 is updated to remove the section and delete its content.

Section 251.301 is updated to remove the section and move its content to Section 251.200.

The paper version of this update transmittal includes revised pages that may be filed in your provider manual. See Section I for instructions on updating the paper version of the manual. For electronic versions, these changes have already been incorporated.

If you have questions regarding this transmittal, please contact the Magellan Pharmacy Call Center at (800) 424-7895.

If you need this material in an alternative format, such as large print, please contact the Program Development and Quality Assurance Unit at (501) 320-6429.

Arkansas Medicaid Health Care Providers – Pharmacy Provider Manual Update PHARMACY-1-17 Page 2

Arkansas Medicaid provider manuals (including update transmittals), official notices, notices of rule making and remittance advice (RA) messages are available for downloading from the Arkansas 'Medicaid website: <u>www.medicaid.state.ar.us</u>.

Thank you for your participation in the Arkansas Medicaid Program.

Stelle Firth 0 Dawn Stehle

Director

**TOC required** 

## 210.000 PROGRAM COVERAGE

#### 211.000 Scope

The Arkansas Medicaid Pharmacy Program conforms to the Medicaid Prudent Pharmaceutical Purchasing Program (MPPPP) that was enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1990. This law requires Medicaid to limit coverage to drugs manufactured by pharmaceutical companies that have signed rebate agreements. A numeric listing of approved pharmaceutical companies and their respective labeler codes is located on the Arkansas Division of Medical Services (DMS) Pharmacy website at <u>https://arkansas.magellanrx.com/provider/documents/</u>. <u>View or print numeric listing of</u> <u>approved pharmaceutical companies and their respective labeler codes</u>. Except for drugs in the categories excluded from coverage, Arkansas Medicaid covers all drug products manufactured by companies with listed labeler codes. Additions or deletions by labelers are submitted to the State by the Centers for Medicare and Medicaid Services (CMS), the website will be updated.

The Arkansas Medicaid Program will cover the following drug categories:

A. Prescription drugs are covered by the Arkansas Medicaid Program pursuant to an order from an authorized prescriber. The Drug Listing located on the DMS Pharmacy website at <u>https://arkansas.magellanrx.com/provider/documents/</u> lists those products covered by the Arkansas Medicaid Program that have a State Actual Acquisition Cost (SAAC).

As changes are made to the drug coverage, providers will be notified of the revisions.

B. Over-the-counter items are listed on the website at <u>https://arkansas.magellanrx.com/provider/documents/</u>. These items are covered only if they contain an appropriate National Drug Code on their label and are manufactured by a company that has signed a rebate agreement. Over-the-counter items are not covered for long-term care facility residents. <u>View or print a list of over-the-counter items</u>.

The Arkansas Medicaid Program will reimburse pharmacies the cost and administration fee for selected vaccines for Medicaid beneficiaries age 19 and older. For a complete list of covered vaccines and CMS-1500 billing instructions, please refer to

<u>https://arkansas.magellanrx.com/provider/docs/rxinfo/Pharmacy%20Vaccine.pdf</u>. A prescription order from an authorized prescriber must be on file; however, no primary care physician (PCP) referral is required to administer the vaccines.

These vaccines are payable for Medicaid-eligible beneficiary age 19 years and older. The influenza virus vaccine is limited to one per state fiscal year (July through June). The pneumococcal polysaccharide vaccine is limited to one every ten years.

The Arkansas Medicaid Program will reimburse pharmacies the administration fee for selected vaccines that are obtained through the Vaccine for Children Program (VFC) or ARKids-B SCHIP Vaccine program. Please refer to section 292.950 of the Physician manual for VFC vaccines billing procedures and section 262.430 for ARKids-B SCHIP vaccine. A prescription order from an authorized prescriber must be on file; however, no primary care physician (PCP) referral is required to administer the vaccines. All Arkansas State Board of Pharmacy laws and regulations will apply.

Effective 8/1/15, ARKids-B beneficiaries are no longer eligible for the VFC program. However, providers are still able to obtain vaccines to administer to ARKids-B beneficiaries by contacting the Arkansas Department of Health (ADH) and indicating the need to order "ARKids-B SCHIP vaccines or Vaccines for Children (VFC)." VFC vaccines can also still be obtained by contacting ADH. For dates of service on or after 8/1/15, modifier "SL" will be required when billing for the

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administration of SCHIP vaccines to ARKids-B beneficiaries. Modifier EBTJ is required when billing for administration of VFC vaccines for ARKids-A beneficiaries.

Medicaid will reimburse the Medicare deductible and/or coinsurance for all beneficiaries receiving both Medicare and Medicaid benefits in reference to vaccines.

Pharmacies must use the CMS-1500 claim form when billing Medicaid for these vaccines.

#### 217.000 Federal Public Health Service's 340B Drug Pricing Program

4-1-17

All covered entities that participate in the Federal Public Health Service's 340B Drug Pricing Program (340B) that carve Arkansas Medicaid into the 340B program are required to bill Arkansas Medicaid using their 340B Actual Invoice Price for drugs.

- A. Covered entities that bill Arkansas Medicaid for physician administered drugs including specialty drugs are required to bill Arkansas Medicaid using their 340B Actual Invoice Price.
- B. Pharmacies are required to bill Arkansas Medicaid using their 340B Actual Invoice Price for Covered Legend and non-legend drugs, including specialty drugs, purchased through the Federal Public Health Service's 340B Drug Pricing Program (340B). The 340B covered entity pharmacies that carve Medicaid into the 340B Drug Pricing Program will be reimbursed at the 340B Actual Invoice Price plus the established professional dispensing fee minus the beneficiary's copayment. The 340B pharmacies will identify on claim submission using the National Council for Prescription Drug Programs (NCPDP) indicator for drugs purchased through the 340B program. Drugs purchased outside the 340B program shall be submitted without the NCPDP 340B claim indicator and will be reimbursed using the lesser of methodology plus the established professional dispensing fee minus the beneficiary's copayment. All applicable federal and state supplemental rebates will be applied to claims submitted without the NCPDP 340B claim indicator. The State will not recognize 340B contract pharmacies. The 340B contract pharmacies are required to carve Medicaid claims out of the 340B Drug Pricing Program. Claims exceeding the 340B ceiling price as published or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA) will be subject to audit and may reject at point of sale.

Pharmacy providers who submit NCPDP claims to the Arkansas Medicaid Program on or after January 1, 2012 will be required to send value 07, 08 or 13 in the Basis of Cost Determination field (423-DN). The 340B providers have contractual agreements with federally qualified 340B entities, enabling special purchase of medication at federal bid pricing. These medications are reserved for only beneficiaries meeting the federal definition of 340B patients. Claims for prescriptions filled with medications purchased through the 340B program will carry the 08 value (340B Pricing) in the Basis of Cost Determination Field. Claims submitted with usual and customary pricing will carry the 07 value (Usual and Customary Pricing) in this field. Claims for prescriptions filled with non-340B purchased medication AND given a special price will carry the 13 value (Special Pricing) in this field.

#### 219.000 Use of Generic Drugs

4-1-17

When a pharmacist receives a prescription for a brand- or trade-name drug, the pharmacist must

A. Dispense the lower-cost generically equivalent drug product, when available. However, this does not prevent the beneficiary from purchasing the brand- or trade-name product if they choose to pay for the prescription. B. If the brand-name drug has a federal upper limit (FUL), State Actual Acquisition Cost (SAAC) or generic NADAC rate, the pharmacist may dispense the brand-name product but will only be reimbursed at the applicable FUL, SAAC or generic NADAC rate.

# 250.000 REIMBURSEMENT

## 251.000 Method of Reimbursement

4-1-17

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:

- 1. Brand Drugs
  - a. The usual and customary charge to the public or submitted ingredient cost

OR

b. The National Average Drug Acquisition Cost (NADAC), as defined in B, 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 C, plus the established professional dispensing fee
- 2. Generic Drugs
  - a. The usual and customary charge to the public or submitted ingredient cost **OR**
  - b. The National Average Drug Acquisition Cost (NADAC), as defined in B, plus the established professional dispensing fee

OR

C.

3.

- The ACA Federal Upper Limit (FUL) plus the established professional dispensing fee
- OR
- d. The calculated State Actual Acquisition Cost (SAAC), as defined in C, plus the established professional dispensing fee
- 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.

4. 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).

- 5. 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.

- 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)].
- 6. 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 no more than 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 reimbursed by the encounter rate except in the case of implantable contraceptive capsules, intrauterine devices and contraceptive injections in which case reimbursed by the encounter rate except in the case of implantable

- 7. Clotting Factor
  - 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).

## 8. Drugs Purchased at Nominal Price

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

- B. The National Average Drug Acquisition Cost (NADAC) is a pricing benchmark published by CMS that calculates ingredient average acquisition costs experienced by retail community providers across the country. When Brand and Generic NADACs are available for the same ingredient, reimbursement will be based on the Generic NADAC except in the case of Preferred Brand Drugs. The allowed ingredient cost for Preferred Brand Medications shall be reimbursed on the lesser of the Brand NADAC, WAC or SAAC.
- C. State Actual Acquisition Cost 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). The SAAC was previously referred to as State Upper Limit (SUL), Generic Upper Limit (GUL), Maximum Allowed Cost (MAC), Cap Upper Limit (CAP).

- D. Investigational drugs are excluded from coverage.
- E. 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:
  - 1.. Brand and Non-preferred Brand = \$9.00
  - 2. Brand Preferred and Generic Medication drug = \$10.50

Drug pricing files are updated weekly.

#### 251.200 Brand Medically Necessary Override

4-1-17

The prescriber must determine whether the Medicaid beneficiary meets the required conditions to override an Upper Limit (FUL, SAAC, Generic NADAC). The prescriber must also complete the required MedWatch (see below) documentation to allow a prior authorization (PA) for a "Brand Medically Necessary" override of the Upper Limit to reimburse at the brand name reimbursement rate.

MedWatch is the Food and Drug Administration (FDA) Safety Information and Adverse Event Reporting Program that allows healthcare professionals to report serious problems that they suspect are associated with certain drugs they prescribe.

The following criteria must be met to override the Upper Limit when calculating the allowable amount of reimbursement:

- A. For MedWatch drugs, the following conditions are required for approval of a Brand Medically Necessary override:
  - 1. The prescriber shall establish that the beneficiary's condition meets the definition provided for the medical necessity of dispensing any brand name drug when a generic equivalent is available.

In the context of this policy, "Brand Medically Necessary" is defined as the necessity to prescribe and dispense a brand name medication when use of a generic product has resulted in adverse reaction(s) to the generic, allergic reaction(s) to the generic or therapeutic failure of the generic.

- a. Adverse reaction caused by a generic must meet one of the following criteria:
  - 1.Life threatening
  - 2.Hospitalization
  - 3.Disability
  - 4. Required intervention to prevent impairment or damage
- b. Allergic reaction is defined as when an allergen is present in a generic drug that is not present in a brand drug resulting in a hypersensitive reaction.
- c. Therapeutic failure is defined as, clinical failure due to the beneficiary's suboptimal plasma drug concentration for the generic drug when compared to published full pharmacokinetic profiles for the brand name drug.
- 2. The prescriber shall submit documentation to Magellan using the FDA MedWatch and the MedWatch Patient Information Request forms to support dispensing a brand

name medication instead of the generic equivalent. The MedWatch Patient Information Request form can be found: https://arkansas.magellanrx.com/provider/docs/rxinfo/ptreguest.pdf.

 When a MedWatch drug is approved for a Brand Medically Necessary override, the Magellan Pharmacy Help Desk will contact the pharmacy provider to inform them of the prior authorization number and the date range of the approved PA.

The PA is given for up to one year for MedWatch Drugs.

All prescriptions must be on file for review by auditors from the Division of Medical Services or their designated agents.

If the criteria stated above are met and the pharmacy claim is submitted with a code of "1" in the dispense as written (DAW) field, the prescription will be priced using the Brand NADAC (or WAC when applicable) for the specific product dispensed rather than the Upper Limit rate.

B. Pharmacy providers can request a review of a specific SAAC associated to a paid claim by completing the AR Medicaid Price Research Request Form and faxing it to the number listed on the form. This form can be found on the Arkansas Medicaid Pharmacy website: <u>https://arkansas.magellanrx.com/provider/docs/rxinfo/AR Medicaid SMAC Price R esearch Request Form.docx</u>.

#### Pharmacy

## **TOC required**

# 210.000 PROGRAM COVERAGE

## 211.000 Scope

The Arkansas Medicaid Pharmacy Program conforms to the Medicaid Prudent Pharmaceutical Purchasing Program (MPPPP) that was enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1990. This law requires Medicaid to limit coverage to drugs manufactured by pharmaceutical companies that have signed rebate agreements. A numeric listing of approved pharmaceutical companies and their respective labeler codes is located on the Arkansas Division of Medical Services (DMS) Pharmacy website at <a href="https://arkansas.magellanrx.com/provider/documents/">https://arkansas.magellanrx.com/provider/documents/</a>. View or print numeric listing of approved pharmaceutical companies and their respective labeler codes. Except for drugs in the categories excluded from coverage, Arkansas Medicaid covers all drug products manufactured by companies with listed labeler codes. Additions or deletions by labelers are submitted to the State by the Centers for Medicare and Medicaid Services (CMS), the website will be updated.

The Arkansas Medicaid Program will cover the following drug categories:

A. Prescription drugs are covered by the Arkansas Medicaid Program pursuant to an order from an authorized prescriber. The <u>Multisource</u> Drugs Listing located on the DMS Pharmacy website at <u>https://arkansas.magellanrx.com/provider/documents/</u> lists those products covered by the Arkansas Medicaid Program that have a <u>State Actual Acquisition</u> <u>Cost (SAAC).generic upper limit See Section 251.300 for an explanation of generic upper limit.</u>

As changes are made to the drug coverage, providers will be notified of the revisions.

B. Over-the-counter items are listed on the website at <u>https://arkansas.magellanrx.com/provider/documents/</u>. These items are covered only if they contain an appropriate National Drug Code on their label and are manufactured by a company that has signed a rebate agreement. Over-the-counter items are not covered for long-term care facility residents. <u>View or print a list of over-the-counter items.</u>

The Arkansas Medicaid Program will reimburse pharmacies the cost and administration fee for selected vaccines for Medicaid beneficiaries age 19 and older. For a complete list of covered vaccines and CMS-1500 billing instructions, please refer to

https://arkansas.magellanrx.com/provider/docs/rxinfo/Pharmacy%20Vaccine.pdf. A prescription order from an authorized prescriber must be on file; however, no primary care physician (PCP) referral is required to administer the vaccines.

These vaccines are payable for Medicaid-eligible beneficiary age 19 years and older. The influenza virus vaccine is limited to one per state fiscal year (July through June). The pneumococcal polysaccharide vaccine is limited to one every ten years.

The Arkansas Medicaid Program will reimburse pharmacies the administration fee for selected vaccines that are obtained through the Vaccine for Children Program (VFC) or ARKids-B SCHIP Vaccine program. Please refer to section 292.950 of the Physician manual for VFC vaccines billing procedures and section 262.430 for ARKids-B SCHIP vaccine. A prescription order from an authorized prescriber must be on file; however, no primary care physician (PCP) referral is required to administer the vaccines. All Arkansas State Board of Pharmacy laws and regulations will apply.

Effective 8/1/15, ARKids-B beneficiaries are no longer eligible for the VFC program. However, providers are still able to obtain vaccines to administer to ARKids-B beneficiaries by contacting the Arkansas Department of Health (ADH) and indicating the need to order "ARKids-B SCHIP"

<del>11-1-15<u>4-1-</u> <u>17</u></del>

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vaccines or Vaccines for Children (VFC)." VFC vaccines can also still be obtained by contacting ADH. For dates of service on or after 8/1/15, modifier "SL" will be required when billing for the administration of SCHIP vaccines to ARKids-B beneficiaries. Modifier EBTJ is required when billing for administration of VFC vaccines for ARKids-A beneficiaries.

Medicaid will reimburse the Medicare deductible and/or coinsurance for all beneficiaries receiving both Medicare and Medicaid benefits in reference to vaccines.

Pharmacies must use the CMS-1500 claim form when billing Medicaid for these vaccines.

#### 217.000 Federal Public Health Service's 340B Drug Pricing Program

<del>10-1-16<u>4-1-</u> 17</del>

All covered entities that participate in the Federal Public Health Service's 340B Drug Pricing Program (340B) that carve Arkansas Medicaid into the 340B program are required to bill Arkansas Medicaid using their 340B Actual Invoice Price for drugs.

- A. Covered entities that bill Arkansas Medicaid for physician administered drugs including specialty drugs are required to bill Arkansas Medicaid using their 340B Actual Invoice Price.
- Pharmacies are required to bill Arkansas Medicaid using their 340B Actual Invoice Price Β. for Covered Legend and non-legend drugs, including specialty drugs, purchased through the Federal Public Health Service's 340B Drug Pricing Program (340B). For drugs purchased through the Federal Public Health Service's 340B Drug Pricing Program, the submitted ingredient cost means the 340B purchase price. The 340B covered entity pharmacies that carve Medicaid into the 340B Drug Pricing Program will be reimbursed as defined above at the 340B Actual Invoice Price plus up to the established professional dispensing fee minus the beneficiary's copayment. The 340B pharmacies will identify on claim submission using the National Council for Prescription Drug Programs (NCPDP) indicator for drugs purchased through the 340B program. Drugs purchased outside the 340B program shall be submitted without the NCPDP 340B claim indicator and will be reimbursed using the lesser of methodology plus up to the established professional dispensing fee minus the beneficiary's copayment. All applicable federal and state supplemental rebates will be applied to claims submitted without the NCPDP 340B claim indicator. The State will not recognize 340B contract pharmacies. The 340B contract pharmacies are required to carve Medicaid claims out of the 340B Drug Pricing Program. Claims exceeding the 340B ceiling price as published or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA) will be subject to audit and may reject at point of sale.

Pharmacy providers who submit NCPDP claims to the Arkansas Medicaid Program on or after January 1, 2012 will be required to send value 07, 08 or 13 in the Basis of Cost Determination field (423-DN). The 340B providers have contractual agreements with federally qualified 340B entities, enabling special purchase of medication at federal bid pricing. These medications are reserved for only beneficiaries meeting the federal definition of 340B patients. Claims for prescriptions filled with medications purchased through the 340B program will carry the 08 value (340B Pricing) in the Basis of Cost Determination Field. Claims submitted with usual and customary pricing will carry the 07 value (Usual and Customary Pricing) in this field. Claims for prescriptions filled with non-340B purchased medication AND given a special price will carry the 13 value (Special Pricing) in this field.

#### 219.000 Use of Generic Drugs



When a pharmacist receives a prescription for a brand- or trade-name drug, the pharmacist must

4-1-0717

A. Dispense the lower-cost generically equivalent drug product, when available. However, this does not prevent the beneficiary from purchasing the brand- or trade-name product if they choose to pay for the prescription.

or

B. If the brand-name drug has a federal <u>upper limit (FUL)</u>, <u>State Actual Acquisition Cost</u> (<u>SAAC</u>) or <u>generic NADAC rate</u> or <u>state generic-upper-limit price</u>, the pharmacist may dispense the brand-name product but will only be reimbursed at the <u>applicable FUL</u>, <u>SAAC</u> or <u>generic NADAC rate.generic upper limit</u>. (<u>See</u> <u>https://arkansas.magellanrx.com/provider/documents/</u> for an explanation of generic upper limit.)

## 250.000 REIMBURSEMENT

### 251.000 Method of Reimbursement

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:

## 1. Brand Drugs

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

## <u>OR</u>

b. The National Average Drug Acquisition Cost (NADAC), as defined in B, plus the established professional dispensing fee

## <u>OR</u>

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

## <u>OR</u>

- d. The calculated State Actual Acquisition Cost (SAAC), as defined in C, plus the established professional dispensing fee
- 2. Generic Drugs
  - a. The usual and customary charge to the public or submitted ingredient cost
  - OR
  - b. The National Average Drug Acquisition Cost (NADAC), as defined in B, plus the established professional dispensing fee

## OR

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

## <u>OR</u>

- d. The calculated State Actual Acquisition Cost (SAAC), as defined in C, plus the established professional dispensing fee
- 3. 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.
- 4. 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).
	5. 340B Drug Pricing Program
	<ul> <li>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.</li> <li>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</li> </ul>
	Price (AMP) minus Unit Rebate Amount (URA)].
	<ul> <li>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. 1396-6 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 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 no to 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.</li> <li>7. Clotting Factor</li> </ul>
	<ul> <li>Pharmacies dispensing Antihemophilic Factor products will be reimbursed at</li> </ul>
<	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).
	<ul> <li>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).</li> </ul>
	8. Drugs Purchased at Nominal Price
	Facilities purchasing drugs at Nominal Price (outside of 340B or FSS) shall be reimbursed by their actual acquisition cost.
<u>B</u> .	The National Average Drug Acquisition Cost (NADAC) is a pricing benchmark published by
<u></u> .	CMS that calculates ingredient average acquisition costs experienced by retail community providers across the country. When Brand and Generic NADACs are available for the

mannacy		Section
1	same ingredient, reimbursement will be based on the Generic NADAC exc	ont in the case
	of Preferred Brand Drugs. The allowed ingredient cost for Preferred Brand	
	shall be reimbursed on the lesser of the Brand NADAC, WAC or SAAC.	Weulcations
	shall be reimbursed of the lesser of the brand habao, who of SAAO.	
C.	State Actual Acquisition Cost shall apply to certain drugs identified adminis	tratively.
	judicially or by a federal agency as having a published price exceeding the	
	The calculated SAAC shall be obtained from actual acquisition costs from i	
	resources, if available. Depending on the variance, either the highest acquired available.	
	average of the acquisition costs or invoice price shall be used in determinin	
	When Brand and Generic drugs are available for the same ingredient, reim	
	be based on the Generic State Actual Acquisition Cost (SAAC). The SAAC	
	referred to as State Upper Limit (SUL), Generic Upper Limit (GUL), Maxim	
	Cost (MAC), Cap Upper Limit (CAP).	aminiation
D.	Investigational drugs are excluded from coverage.	
Ε.	The Professional Dispensing Fee for covered outpatient legend and non-le	gend drugs
_	shall take into consideration the State's Preferred Drug List status for the d	ing being
	dispensed and equals the average professional dispensing fee in the aggre	
	1 Brand and Non-preferred Brand = \$9.00	
	2. Brand Preferred and Generic Medication drug = \$10.50	
Mee	dicaid payments are made according to federal regulations. For each prescri	<del>ption,</del>
	nbursement is based on one (1) of the following	
A	<ul> <li>The State/Federal Generic Upper Limit (GUL) plus a dispensing fee based</li> </ul>	on the formula:
	State/Federal GUL + \$5.51. (Dispensing fee equals \$5.51.)	
	-Or	
B	The lowest of the pharmacy's usual and customary charge to the general p	ublic or the
<b>D</b> .	Estimated Acquisition Cost (EAC) plus dispensing fee, where EAC is defin	
	Estimated Acquisition Cost (Ester plus disperising fee, where Erte is defin	cu us.
	1. The Estimated Acquisition Cost (EAC) of the brand name drug dispe	nsed plus
	dispensing fee based on the formula: EAC + \$5.51. (EAC equals Ave	erage Wholesale
	Price [AWP] minus 14%. Dispensing fee equals \$5.51.)	
	and	
	2. The Estimated Acquisition Cost (EAC) of the generic drug dispensed	plus dispensing
	tee is based on the formula: EAC + \$5.51. (EAC equals Average Wi	holesale Price
	[AWP] minus 20%. Dispensing fee equals \$5.51.)	
	additional differential dispensing fee of \$2.00 will be paid on generic drugs th	at are not limited
by a	a State or Federal generic upper limit.	
	a China film and a task and a task a	
Dru	ig pricing files are updated weekly.	
054 000		44 45 44
251.200	Estimated Acquisition Cost	<del>11-15-11</del>
Eor	Arkansas Medicaid reimbursement purposes, the estimated acquisition cost	(EAC) for a
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For Arkansas Medicaid reimbursement purposes, the estimated acquisition cost (EAC) for a brand name drug is the average wholesale price (AWP) minus 14%. The EAC for a generic drug is the AWP minus 20%. The drug pricing file used in the claims processing system contains all package sizes available for each covered drug product. The AWP pricing information is updated weekly with current information from the national compendia.

Drug cost is calculated according to the package size purchased by each individual provider. For example, if a pharmacy buys a particular drug in a bottle of 100, the pharmacy provider is to

A

1.

bill Medicaid with the National Drug Code (NDC) number for the 100-unit package size; the drug product cost is calculated based on the 100-unit size. If another pharmacy buys the same drug in a bottle of 1000, that pharmacy provider is to bill Medicaid with the NDC number for the 1000-unit package size; the drug cost is calculated based on the 1000-unit size.

Drug manufacturer/labelers are responsible for timely notification to the national compendia of any product and price revisions. The drug pricing file is updated weekly according to the information provided to the national compendia by the manufacturer/labelers. The EAC prices in the Medicaid Program may not correlate exactly with the list price from all wholesalers due to variations in the marketplace.

#### 251.300 Generic Upper Limit Cost

3-14-15

The generic upper limit (GUL) price is the maximum drug cost used to compute reimbursement for multiple-source drugs unless the provisions for a generic-upper-limit override have been met.

For several multiple-source drugs, the federal government requires that payment under the Medicaid Program be based on a generic-upper-limit cost that is established by CMS. For other multiple-source drugs, the state agency has determined which drugs will be on the Arkansas generic-upper-limit list and is responsible for setting the maximum price the provider may use as his cost for that drug. The generic upper limit is listed on the Arkansas Medicaid Pharmacy website, https://arkansas.magellanrx.com/provider/docs/rxinfo/gul.pdf

Generic upper limit is based on price per unit (ml, gm, tablet, capsule, etc.) in the commonly available quantity.

#### 251.301200 Generic Upper Limit Override Brand Medically Necessary Override 3-14-154-1-17

The prescriber must determine whether the Medicaid beneficiary meets the required conditions to override an <u>Upper Limit (FUL\_SAAC, Generic NADAC)</u>-generic upper limit (GUL) cost of a drug. The prescriber must also complete the required MedWatch (see below) documentation to allow a prior authorization (PA) for a "Brand Medically Necessary" override of the <u>GUL-Upper</u> <u>Limit</u> to reimburse at the brand name reimbursement rate.

MedWatch is the Food and Drug Administration (FDA) Safety Information and Adverse Event Reporting Program that allows healthcare professionals to report serious problems that they suspect are associated with certain drugs they prescribe.

The following criteria must be met to override the GUL-Upper Limit when calculating the allowable amount of reimbursement:

For MedWatch drugs, the following conditions are required for approval of a Brand Medically Necessary override:

The prescriber shall establish that the beneficiary's condition meets the definition provided for the medical necessity of dispensing any brand name drug when a generic equivalent is available.

In the context of this policy, "Brand Medically Necessary" is defined as the necessity to prescribe and dispense a brand name medication when use of a generic product has resulted in adverse reaction(s) to the generic, allergic reaction(s) to the generic or therapeutic failure of the generic.

- a. Adverse reaction caused by a generic must meet one of the following criteria:
  - 1.Life threatening
  - 2.Hospitalization
  - 3.Disability
  - 4.Required intervention to prevent impairment or damage

- b. Allergic reaction is defined as when an allergen is present in a generic drug that is not present in a brand drug resulting in a hypersensitive reaction.
- c. Therapeutic failure is defined as, clinical failure due to the beneficiary's suboptimal plasma drug concentration for the generic drug when compared to published full pharmacokinetic profiles for the brand name drug.
- The prescriber shall submit documentation to Magellan using the FDA MedWatch and the MedWatch Patient Information Request forms to support dispensing a brand name medication instead of the generic equivalent. The MedWatch Patient Information Request form can be found: https://arkansas.magellanrx.com/provider/docs/rxinfo/ptrequest.pdf.
- 3. When a MedWatch drug is approved for a Brand Medically Necessary override, the Magellan Pharmacy Help Desk will contact the pharmacy provider to inform them of the prior authorization number and the date range of the approved PA.

The PA is given for up to one year for MedWatch Drugs.

All prescriptions must be on file for review by auditors from the Division of Medical Services or their designated agents.

If the criteria stated above are met and the pharmacy claim is submitted with a code of "1" in the dispense as written (DAW) field, the prescription will be priced using the <u>EAC priceBrand</u> <u>NADAC (or WAC when applicable)</u> for the specific product dispensed rather than the <u>generic</u> <u>uUpper ILimit pricerate</u>.

B. Pharmacy providers can request a review of a specific <u>GUL\_SAAC</u> associated to a paid claim by completing the AR Medicaid Price Research Request Form and faxing it to the number listed on the form. This form can be found on the Arkansas Medicaid Pharmacy website:

https://arkansas.magellanrx.com/provider/docs/rxinfo/AR Medicaid SMAC Price R esearch Request Form.docx.



TO:

Division of Medical Services

**Program Development & Quality Assurance** 

P.O. Box 1437, Slot S295 · Little Rock, AR 72203-1437 501-320-6428 · Fax: 501-404-4619 TDD/TTY: 501-682-6789



Arkansas Medicaid Health Care Providers – All

EFFECTIVE DATE: April 1, 2017

SUBJECT: Provider Manual Update Transmittal SecI-1-17

REMOVE		INSERT	
Section	Effective Date	Section	Effective Date
142.200	9-15-09	142.200	4-1-17

## Explanation of Updates

Section 142.200, Conditions Related to Billing for Medicaid Services, has been updated to include the statement that all covered entities that participate in the Federal Public Health Service's 340B Drug Pricing Program (340B) that carve Arkansas Medicaid into the 340B program are required to bill Arkansas Medicaid using their 340B actual invoice price for drugs.

The paper version of this update transmittal includes revised pages that may be filed in your provider manual. See Section I for instructions on updating the paper version of the manual. For electronic versions, these changes have already been incorporated.

If you have questions regarding this transmittal, please contact the Hewlett Packard Enterprise Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and Out-of-State at (501) 376-2211.

If you need this material in an alternative format, such as large print, please contact the Program Development and Quality Assurance Unit at (501) 320-6429.

Arkansas Medicaid provider manuals (including update transmittals), official notices, notices of rule making and remittance advice (RA) messages are available for downloading from the Arkansas Medicaid website: <u>www.medicaid.state.ar.us</u>.

Thank you for your participation in the Arkansas Medicaid Program.

TAN Dawn Stehle

Dawn Stehle Director

### TOC is required

#### 142.200 Conditions Related to Billing for Medicaid Services

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4-1-17
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- A. Any covered service performed by a provider must be billed only after the service has been provided. No service or procedure may be pre-billed.
- B. Endorsement of the provider check issued by the Medicaid fiscal agent certifies that the services were rendered by or under the direct supervision of the provider as billed.
- C. It is the responsibility of each provider to be alert to the possibility of third party sources of payment and to report receipt of funds from these sources to DMS.
- D. Each provider must accept Medicare assignment under Title XVIII (Medicare) in order to receive payment under Title XIX (Medicaid) for any Medicare deductible or coinsurance due and payable under Title XIX (Medicaid). See Section 142.700 for more and detailed information.
- E. Each provider must accept payment from Medicaid as payment in full for covered services, make no additional charges and accept no additional payment from the beneficiary for these services.
- F. Medicaid providers may not charge beneficiaries for the completion and submission of a Medicaid claim form. If the provider agrees to accept the patient as a Medicaid beneficiary and agrees to bill Medicaid for the services rendered, the beneficiary may not be charged for this billing procedure.
- G. Claims for services provided to eligible Medicaid beneficiaries must be submitted to the Medicaid fiscal agent within twelve months from the date of service.
- H. Federal Public Health Service's 340B Drug Pricing Program: All covered entities that participate in the Federal Public Health Service's 340B Drug Pricing Program (340B) that carve Arkansas Medicaid into the 340B program are required to bill Arkansas Medicaid using their 340B actual invoice price for drugs. Reimbursement shall be no more than the 340B ceiling price.

#### TOC is required

#### 142.200 Conditions Related to Billing for Medicaid Services

#### <del>9-15-09<u>4-1-</u> <u>17</u></del>

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