## 142.200 Conditions Related to Billing for Medicaid Services 4-1-23

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 information and details.

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 (12) months from the date of service.

H. Federal Public Health Service's 340B Drug Pricing Program: All covered entities (except Federally Qualified Health Centers) 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 covered outpatient drugs. Reimbursement shall be no more than the 340B ceiling price. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed. A covered outpatient drug includes outpatient drugs and drugs used in connection with an inpatient or outpatient service provided by a hospital. Covered entities (except Federally Qualified Health Centers) must also identify all 340B drug claims using the medical modifiers JG or TB. Medical drug claims from covered 340B entities without the modifiers JG or TB will be considered non-340B drug claims and will be subject to rebate invoicing.

I. 340B drug claims will be subject to post payment review. Providers are responsible for maintaining documentation to support billed amounts.

## 217.000 Federal Public Health Service's 340B Drug Pricing Program 4-1-23

All covered entities that participate in the Federal Public Health Service's 340B Drug Pricing Program 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. The 340B covered entity pharmacies that carve Medicaid into the 340B Drug Pricing Program will be reimbursed the lesser of the 340B Actual Invoice Price or the 340B ceiling price [provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)] plus the established professional dispensing fee, minus the beneficiary's copayment. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed. 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.

## 251.000 Method of Reimbursement 4-1-23

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

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

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.

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) plus zero percent (+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) plus zero percent (+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 by pharmacies that carve Medicaid into the 340B Drug Pricing Program, shall be reimbursed the lesser of the 340B Actual Invoice Price or the 340B ceiling price [provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)] plus the established professional dispensing fee. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed. 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 the lesser of the 340B Actual Invoice Price or the 340B ceiling price [provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)]. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed. Physician administered drugs include outpatient drugs and drugs used in connection with an inpatient or outpatient service provided by a hospital. Covered entities must also identify all 340B drug claims using the medical modifiers JG or TB. Medical drug claims from covered 340B entities, without the modifiers JG or TB, will be considered non-340B drug claims and will be subject to rebate invoicing.

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 at the actual acquisition cost.

7. 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) plus zero percent (+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 by pharmacies that carve Medicaid into the 340B Drug Pricing Program shall be reimbursed at the lesser of the 340B actual invoice price or the 340B ceiling price {provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)] plus the established professional dispensing fee. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed.

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), and 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 = Nine Dollars ($9.00); or

   2. Brand Preferred and Generic Medication drug = Ten Dollars and Fifty Cents ($10.50).

Drug pricing files are updated weekly.

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 are defined as drugs not available for dispensing in all retail pharmacies based on price or separate agreements between manufacturer and pharmacy. Limited Access Drugs 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) plus zero percent (+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 the lesser of the 340B actual invoice price or the 340B ceiling price [provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)] plus the established professional dispensing fee. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed. 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 the lesser of the 340B actual invoice price or the 340B ceiling price [provided or calculated by Average Manufacturer Price (AMP) minus Unit Rebate Amount (URA)]. The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed.

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**)** plus zero percent (+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 the lesser of methodology for the allowed ingredient cost shall be the 340B actual invoice price, Wholesale Acquisition Cost (WAC) plus zero percent (+0%) or State Actual Acquisition Cost (SAAC). The 340B actual invoice price for each drug reimbursement covered under this program must be submitted to the Department prior to any claims being processed.

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 fee schedule**.** If the Medicare rate is not available**,** then other published pricing Average Wholesale Price (AWP) less five percent (-5%) 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).

14. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known Hospital Associations-possibly against due to charge master costs to add modifiers.

## FINANCIAL IMPACT STATEMENT

**PLEASE ANSWER ALL QUESTIONS COMPLETELY**

**DEPARTMENT** Department of Human Services

**DIVISION** Division of Medical Services

**PERSON COMPLETING THIS STATEMENT** Jason Callan

**TELEPHONE** 501-320-6540 **FAX** 501-682-8155 **EMAIL:** Jason.Callan@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** 340B Modifiers on Physician Administered Drugs

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☒ No ☐

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes ☒ No ☐

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☒ No ☐

   If an agency is proposing a more costly rule, please state the following:

   (a) How the additional benefits of the more costly rule justify its additional cost;

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

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

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

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

   (a) What is the cost to implement the federal rule or regulation?

| **Current Fiscal Year** | | **Next Fiscal Year** | |
|---|---|---|---|
| General Revenue | $ | General Revenue | $ |

| | | | |
|---|---|---|---|
| Federal Funds | $ | Federal Funds | $ |
| Cash Funds | | Cash Funds | |
| Special Revenue | | Special Revenue | |
| Other (Identify) | | Other (Identify) | |
| Total | $ | Total | $ |

(b) What is the additional cost of the state rule?

| **Current Fiscal Year** | | **Next Fiscal Year** | |
|---|---|---|---|
| General Revenue | ($455,315) | General Revenue | ($607,086) |
| Federal Funds | ($1,149,036) | Federal Funds | ($1,532,048) |
| Cash Funds | | Cash Funds | |
| Special Revenue | | Special Revenue | |
| Other (Identify) | | Other (Identify) | |
| Total | ($1,604,351) | Total | ($2,139,135) |

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**
$ _____

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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**
$ (455,315)

**Next Fiscal Year**
$ (607,086)

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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. -