

## PUBLIC NOTICE

January 11, 2017

Pursuant to 42 C.F.R. Section 447.205, public notice is hereby given to the submission of a Medicaid State Plan Amendment (SPA). The Division of Medicaid, in the Office of the Governor, is submitting SPA 17-0002 Pharmacy Reimbursement. Effective April 1, 2017, and contingent upon approval from the Centers for Medicare and Medicaid Services (CMS), the Division of Medicaid will revise the payment methodology for prescription drugs at point-of-sale (POS) pharmacies and describe reimbursement for 340B covered entities.

1. Mississippi Medicaid SPA 17-0002 Pharmacy Reimbursement is being submitted to revise the payment methodology for the following drugs at POS pharmacies as described below:
  - A. Brand Name drugs – Ingredient cost based on actual acquisition cost (AAC) plus a professional dispensing fee of \$11.29. AAC is defined as the lesser of:
    1. National Average Drug Acquisition Cost (NADAC), or
    2. Wholesale Acquisition Cost (WAC) plus two percent (2%) when no NADAC is available, or
    3. The provider’s usual and customary charge.
  - B. Generic drugs – Ingredient cost based on AAC plus a professional dispensing fee \$11.29. AAC is defined as the lesser of:
    1. NADAC, or
    2. WAC plus two percent (2%) when no NADAC is available, or
    3. The provider’s usual and customary charge.
  - C. Reimbursement for 340B covered entities as described in section 1927(a)(5)(B) of the Act, including an Indian Health Service, tribal and urban Indian pharmacy as follows:
    1. Purchased 340B drugs – Ingredient cost must be no more than the 340B AAC defined as the price at which the covered entity has paid the wholesaler or manufacturer for the outpatient drug plus a professional dispensing fee of \$11.29.
    2. Drugs purchased outside of the 340B program by covered entities – Ingredient cost based on AAC plus a professional dispensing fee of \$11.29. ACC is defined as the lesser of:
      - a. NADAC, or
      - b. WAC plus two percent (2%) when no NADAC, or
      - c. The provider’s usual and customary charge.
    3. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not reimbursed.
  - D. Drugs acquired via the Federal Supply Schedule (FSS) – Ingredient cost based on AAC plus a professional dispensing fee of \$11.29.

- E. Drugs acquired at Nominal Price (outside of 340B or FSS) – Ingredient cost based on AAC plus a professional dispensing fee of \$11.29.
  - F. Specialty drugs not dispensed by a retail community pharmacy and dispensed primarily through the mail – Ingredient cost plus a professional dispensing fee of \$61.14. Ingredient cost is defined as the lesser of:
    - 1. WAC plus zero percent (0%), or
    - 2. The provider’s usual and customary charge.
  - G. Drugs not dispensed by a retail community pharmacy (e.g., institutional or long-term care pharmacy when not included as part of an inpatient stay) – Ingredient cost plus a professional dispensing fee of \$11.29. AAC is defined as the lesser of:
    - 1. NADAC, or
    - 2. WAC plus two percent (2%) when no NADAC is available, or
    - 3. The provider’s usual and customary charge.
  - H. Clotting Factor from Specialty Pharmacies, Hemophilia Treatment Centers (HTCs), Centers of Excellence – Ingredient cost plus a professional dispensing fee of \$0.02 per Unit.
    - 1. For a 340B covered entity:
      - a. Purchased 340B drugs – Ingredient cost must be no more than the 340B AAC defined as the price at which the covered entity has paid the wholesaler or manufacturer for the outpatient drug.
      - b. Drugs purchased outside of the 340B program by covered entities – Ingredient cost is defined as the lesser of WAC minus ten percent (10%) or the provider’s usual and customary charge.
    - 2. For a non-340B covered entity – Ingredient cost is the lesser of WAC minus ten percent (10%) or the provider’s usual and customary charge.
2. Mississippi Medicaid SPA 17-0002 Pharmacy Reimbursement is being submitted to describe reimbursement for 340B covered entities as described in section 1927(a)(5)(B) of the Act, including an Indian Health Service, tribal and urban Indian pharmacy that administer 340B physician administered drugs and implantable drug system devices is as follows:
- A. For drugs purchased through the 340B program, the ingredient cost must be no more than the 340B Actual Acquisition Cost (AAC) defined as the price the covered entity paid the wholesaler or manufacturer for the outpatient drug.
  - B. Drugs purchased outside of the 340B program by covered entities are reimbursed as described on Attachment 4.19-B Page 12a.3 and 12a.4.
  - C. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not reimbursed.
3. The expected economic impact is an annual savings of \$3,353,660 in state dollars and \$9,865,340 in federal dollars. The financial impact was calculated by re-pricing POS

pharmacy utilization data for dates of service June 1, 2015, through May 31, 2016, with paid dates through June 30, 2016, using the Division of Medicaid's current pharmacy reimbursement methodology and comparing it with the new reimbursement methodologies.

4. SPA 17-0002 Pharmacy Reimbursement will enable the Division of Medicaid to be in compliance with the Affordable Care Act (ACA) and 42 C.F.R. Part 447.
5. A copy of the proposed SPA will be available in each county health department office and in the Department of Human Services office in Issaquena County for review. A hard copy can be downloaded and printed from [www.medicaid.ms.gov](http://www.medicaid.ms.gov) or may be requested at [Margaret.Wilson@medicaid.ms.gov](mailto:Margaret.Wilson@medicaid.ms.gov) or 601-359-2081.
6. Written comments will be received by the Division of Medicaid, Office of the Governor, Office of Policy, Walter Sillers Building, Suite 1000, 550 High Street, Jackson, Mississippi 39201, or [Margaret.Wilson@medicaid.ms.gov](mailto:Margaret.Wilson@medicaid.ms.gov) for thirty (30) days from the date of publication of this notice. Comments will be available for public review at the above address and on the Division of Medicaid's website at [www.medicaid.ms.gov](http://www.medicaid.ms.gov).
7. A public hearing on this SPA will not be held.

State of Mississippi

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES –OTHER TYPES OF CARE

Prescribed Drugs

The Division of Medicaid pays reimburses for certain legend and non-legend drugs, as authorized under the State plan, prescribed by a physician or other Mississippi enrolled Medicaid prescribing provider licensed to prescribe drugs as authorized under the program and dispensed by a Mississippi enrolled Medicaid pharmacy licensed pharmacist in accordance with Federal and State laws.

The Mississippi Division of Medicaid Prescription Drug Program conforms to the Medicaid Prudent Pharmaceutical Purchasing Program as set forth in the Omnibus Budget Reconciliation Act of 1990 (OBRA'90) and complies with the Centers for Medicare and Medicaid (CMS) Covered Outpatient Drug Final Rule in accordance with 42 C.F.R. Part 447.

For Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)-eligible beneficiaries under age 21, special exceptions for the use of non-covered drug items may be made in unusual circumstances when prior authorization is given by the Division of Medicaid or designated entity. Medically necessary prescribed drugs for EPSDT-eligible beneficiaries which exceed the limitations and scope for Medicaid beneficiaries, as covered in the State Plan, are reimbursed according to the methodology in the paragraphs below.

I. The Division of Medicaid reimburses the following drugs as described below:

A. Brand Name drugs – Ingredient cost based on actual acquisition cost (AAC) plus a professional dispensing fee of \$11.29. AAC is defined as the lesser of:

1. National Average Drug Acquisition Cost (NADAC), or
2. Wholesale Acquisition Cost (WAC) plus two percent (2%) when no NADAC is available, or
3. The provider's usual and customary charge.

B. Generic drugs – Ingredient cost based on AAC plus a professional dispensing fee \$11.29. AAC is defined as the lesser of:

1. NADAC, or
2. WAC plus two percent (2%) when no NADAC is available, or
3. The provider's usual and customary charge.

C. Reimbursement for 340B covered entities as described in section 1927(a)(5)(B) of the Act, including an Indian Health Service, tribal and urban Indian pharmacy as follows:

1. Purchased 340B drugs – Ingredient cost must be no more than the 340B AAC defined as the price at which the covered entity has paid the wholesaler or manufacturer for the outpatient drug plus a professional dispensing fee of \$11.29.
2. Drugs purchased outside of the 340B program by covered entities – Ingredient cost based on AAC plus a professional dispensing fee of \$11.29. ACC is defined as the lesser of:
  - a. NADAC, or
  - b. WAC plus two percent (2%) when no NADAC, or
  - c. The provider's usual and customary charge.
3. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not reimbursed.

D. Drugs acquired via the Federal Supply Schedule (FSS) – Ingredient cost based on AAC plus a professional dispensing fee of \$11.29.

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- E. Drugs acquired at Nominal Price (outside of 340B or FSS) – Ingredient cost based on AAC plus a professional dispensing fee of \$11.29.
- F. Specialty drugs not dispensed by a retail community pharmacy and dispensed primarily through the mail – Ingredient cost plus a professional dispensing fee of \$61.14. Ingredient cost is defined as the lesser of:
  - 1. WAC plus zero percent (0%), or
  - 2. The provider’s usual and customary charge.
- G. Drugs not dispensed by a retail community pharmacy (e.g., institutional or long-term care pharmacy when not included as part of an inpatient stay) – Ingredient cost plus a professional dispensing fee of \$11.29. AAC is defined as the lesser of:
  - 1. NADAC, or
  - 2. WAC plus two percent (2%) when no NADAC is available, or
  - 3. The provider’s usual and customary charge.
- H. Clotting Factor from Specialty Pharmacies, Hemophilia Treatment Centers (HTCs), Centers of Excellence – Ingredient cost plus a professional dispensing fee of \$0.02 per Unit.
  - 1. For a 340B covered entity:
    - a. Purchased 340B drugs – Ingredient cost must be no more than the 340B AAC defined as the price at which the covered entity has paid the wholesaler or manufacturer for the outpatient drug.
    - b. Drugs purchased outside of the 340B program by covered entities – Ingredient cost is defined as the lesser of WAC minus ten percent (10%) or the provider’s usual and customary charge.
  - 2. For a non-340B covered entity – Ingredient cost is the lesser of WAC minus ten percent (10%) or the provider’s usual and customary charge.

II. The Division of Medicaid does not reimburse for Investigational Drugs.

III. Usual and Customary Charges

The Division of Medicaid defines usual and customary charge as the lowest price the pharmacy would charge to a particular customer if such customer were paying cash for the identical prescription drug services on the date dispensed. This includes any applicable discounts including, but not limited to, senior discounts, frequent shopper discounts, and other special discounts offered to attract customers such as four dollar (\$4.00) flat rate generic price lists. A pharmacy cannot have a usual and customary charge for prescription drug programs that differs from either cash customers or other third-party programs. The pharmacy must submit the accurate usual and customary charge with respect to all claims for prescription drug services.

IV. Overall, the Division of Medicaid’s payment will not exceed the federal upper limit (FUL) based on the NADAC for ingredient reimbursement in the aggregate for multiple source drugs and other drugs including prescription drugs which the prescriber certifies as being medically necessary for a beneficiary.

~~EAC (Estimated Acquisition Cost) is defined as the Division’s estimate of the price generally paid by pharmacies for pharmaceutical products. EAC (Estimated Acquisition Cost) is defined as the Division’s estimate of the price generally paid by pharmacies for pharmaceutical products. EAC may be based on the Average Wholesale Price (AWP) or the Wholesale Acquisition Cost (WAC) or the State Maximum Allowable Cost (SMAC) as described below. The EAC will not be based on the SMAC unless the State prevails in Mississippi Independent Pharmacies Association, et al .v. Division of Medicaid, et.al; Hinds County Chancery Court No. G2008-704 S/2.~~

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~~SMAC reimbursement will apply to certain multi-source drug products that meet therapeutic equivalency, market availability, and other criteria deemed appropriate by the Division of Medicaid. Actual acquisition cost will be determined through the collection and review of pharmacy invoices and other information deemed necessary by the Division and in accordance with applicable State and Federal law. SMAC rates are based on the average actual acquisition cost per drug of pharmacy providers enrolled in the Medicaid Program, adjusted by a multiplier that is 1.3, which ensures that each rate is sufficient to allow reasonable access by providers to the drug at or below the established SMAC rate. The Division will review the rates on no less than an annual basis and adjust them as necessary to reflect prevailing market conditions and to assure reasonable access by providers.~~

~~**A. Brand Name Drugs** (single source, innovator multiple source) — In reimbursing for brand name drugs Medicaid shall pay for:~~

- ~~1.) The lesser of:
  - a.) The provider's usual and customary charge; or
  - b.) The EAC for brand name drugs which is defined as the lesser of:
    - i.) AWP minus 12% plus a dispensing fee of \$3.91; or
    - ii.) WAC plus 9% plus a dispensing fee of \$3.91.~~
- ~~2.) Less the applicable co-payment.~~

~~**B. Multiple Source Generic Drugs** — In reimbursing for multiple source generic drugs, as defined by CMS, Medicaid shall pay:~~

- ~~1.) The lesser of:
  - a.) The provider's usual and customary charge; or
  - b.) The Federal Upper Limit (FUL), if applicable, plus a dispensing fee of \$5.50\*;or
  - e.) The EAC for multiple source drugs which is defined as the lesser of:
    - i.) AWP minus 25% plus a dispensing fee of \$5.50 or
    - ii.) SMAC rate and a dispensing fee of \$5.50\* (except \$4.91 unless the State prevails in Mississippi Independent Pharmacies Association, et al. v. Division of Medicaid, et al.; Hinds County Chancery Court No. G2008-04 S/2..~~
- ~~2.) Less the applicable co-payment.~~

~~\*The dispensing fee for prescriptions to beneficiaries in long-term care facilities for multi-source generic drugs is limited to \$3.91.~~

**C. Other Drugs**

- ~~1.) Reimbursement for covered drugs other than the multiple source drugs  
With CMS upper limits shall not exceed the lesser of:
  - a.) The provider's usual and customary charge; or
  - b.) The EAC for other than multiple source drugs which is defined as the lesser of:
    - i.) AWP minus 12% plus a dispensing fee of \$3.91; or
    - ii.) WAC plus 9% plus a dispensing fee of \$3.91; or
  - iii.) SMAC rate and a dispensing fee of \$3.91.c.) Less the applicable co-payment~~

- ~~2.) Reimbursement for covered non-legend products or over-the-counter products is the less of:
  - a.) The provider's usual and customary charge; or
  - b.) The EAC for multiple source drugs which is defined as the lesser of:~~

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- i) ~~AWP minus 25% plus a dispensing fee of \$3.91 or ii) SMAC rate and a dispensing fee of \$3.91.~~  
e) ~~Less the applicable co-payment~~

2. Professional Dispensing Fee

~~Dispensing fees are determined on the basis of surveys that are conducted periodically by the Division of Medicaid and take into account various pharmacy operational costs. Between surveys, the dispensing fee may be adjusted based on various factors (i.e., CPT, etc.). The dispensing fee of \$3.91 for sole source drugs and \$5.50 for multi source drugs is paid for non-institutionalized beneficiaries. The dispensing fee paid for institutionalized beneficiaries is \$3.91.~~

3. Usual and Customary Charges

~~The provider's usual and customary charge is defined as the charge to the non-Medicaid patient. The state agency obtains the provider's usual and customary charge from the pharmacy invoice. The accuracy of the usual and customary charge is validated by Division staff in the field who conducts on-site audits. Audits of prescription files and usual and customary fee schedules will be the means by which compliance with this stipulation is assured.~~

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4. EPSDT Beneficiaries

~~Prescribed drugs for EPSDT beneficiaries, if medically necessary, which exceed the limitations and scope for Medicaid beneficiaries, as covered in this Plan, are reimbursed according to the methodology in the paragraphs above.~~

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#### Prescribed Drugs

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    3. The provider's usual and customary charge.
  - B. Generic drugs – Ingredient cost based on AAC plus a professional dispensing fee \$11.29. AAC is defined as the lesser of:
    1. NADAC, or
    2. WAC plus two percent (2%) when no NADAC is available, or
    3. The provider's usual and customary charge.
  - C. Reimbursement for 340B covered entities as described in section 1927(a)(5)(B) of the Act, including an Indian Health Service, tribal and urban Indian pharmacy as follows:
    1. Purchased 340B drugs – Ingredient cost must be no more than the 340B AAC defined as the price at which the covered entity has paid the wholesaler or manufacturer for the outpatient drug plus a professional dispensing fee of \$11.29.
    2. Drugs purchased outside of the 340B program by covered entities – Ingredient cost based on AAC plus a professional dispensing fee of \$11.29. ACC is defined as the lesser of:
      - a. NADAC, or
      - b. WAC plus two percent (2%) when no NADAC, or
      - c. The provider's usual and customary charge.
    3. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not reimbursed.
  - D. Drugs acquired via the Federal Supply Schedule (FSS) – Ingredient cost based on AAC plus a professional dispensing fee of \$11.29.



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- E. Drugs acquired at Nominal Price (outside of 340B or FSS) – Ingredient cost based on AAC plus a professional dispensing fee of \$11.29.
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  - G. Drugs not dispensed by a retail community pharmacy (e.g., institutional or long-term care pharmacy when not included as part of an inpatient stay) – Ingredient cost plus a professional dispensing fee of \$11.29. AAC is defined as the lesser of:
    - 1. NADAC, or
    - 2. WAC plus two percent (2%) when no NADAC is available, or
    - 3. The provider’s usual and customary charge.
  - H. Clotting Factor from Specialty Pharmacies, Hemophilia Treatment Centers (HTCs), Centers of Excellence – Ingredient cost plus a professional dispensing fee of \$0.02 per Unit.
    - 1. For a 340B covered entity:
      - a. Purchased 340B drugs – Ingredient cost must be no more than the 340B AAC defined as the price at which the covered entity has paid the wholesaler or manufacturer for the outpatient drug.
      - b. Drugs purchased outside of the 340B program by covered entities – Ingredient cost is defined as the lesser of WAC minus ten percent (10%) or the provider’s usual and customary charge.
    - 2. For a non-340B covered entity – Ingredient cost is the lesser of WAC minus ten percent (10%) or the provider’s usual and customary charge.
- II. The Division of Medicaid does not reimburse for Investigational Drugs.
- III. Usual and Customary Charges  
The Division of Medicaid defines usual and customary charge as the lowest price the pharmacy would charge to a particular customer if such customer were paying cash for the identical prescription drug services on the date dispensed. This includes any applicable discounts including, but not limited to, senior discounts, frequent shopper discounts, and other special discounts offered to attract customers such as four dollar (\$4.00) flat rate generic price lists. A pharmacy cannot have a usual and customary charge for prescription drug programs that differs from either cash customers or other third-party programs. The pharmacy must submit the accurate usual and customary charge with respect to all claims for prescription drug services.
- IV. Overall, the Division of Medicaid’s payment will not exceed the federal upper limit (FUL) based on the NADAC for ingredient reimbursement in the aggregate for multiple source drugs and other drugs including prescription drugs which the prescriber certifies as being medically necessary for a beneficiary.

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**340B Covered Entities Administering 340B Drugs**

Reimbursement for 340B covered entities as described in section 1927(a)(5)(B) of the Act, including an Indian Health Service, tribal and urban Indian pharmacy that administer 340B physician administered drugs and implantable drug system devices is as follows:

1. For drugs purchased through the 340B program, the ingredient cost must be no more than the 340B Actual Acquisition Cost (AAC) defined as the price the covered entity paid the wholesaler or manufacturer for the outpatient drug.
2. Drugs purchased outside of the 340B program by covered entities are reimbursed as described on Attachment 4.19-B Page 12a.3 and 12a.4.
3. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not reimbursed.