PUBLIC NOTICE

June 29, 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 18-0011 Physician Administered Drugs. Effective July 1, 2018, and contingent upon approval from the Centers for Medicare and Medicaid Services (CMS), the Division of Medicaid will begin reimbursing for physician administered drugs under the pharmacy benefit to increase beneficiary access.

1. Mississippi Medicaid SPA 18-0011 Physician Administered Drugs is being submitted to include the payment methodology for physician administered drugs under the pharmacy benefit according to the following hierarchy:
   a. National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee of $11.29, or
   b. Wholesale Acquisition Cost (WAC) plus zero percent (0%) plus a professional dispensing fee of $11.29 when no NADAC is available, or
   c. A rate set by the Division of Medicaid's rate-setting vendor plus a professional dispensing fee of $11.29 when no NADAC or WAC are available, or
   d. The provider's usual and customary charge.

2. The Division of Medicaid expects to realize a savings in expenditures due to the increased beneficiary access to, but not limited to, long-acting reversible contraceptives (LARCs), pregnancy maintaining agents, injectable atypical antipsychotics agents, and chemical dependency treatment agents.

3. The Division of Medicaid is submitting SPA 18-0011 Physician Administered Drugs to comply with 42 C.F.R. § 447.518 and Senate Bill 2836 passed during the 2018 legislative session.

4. 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 or may be requested at Margaret.Wilson@medicaid.ms.gov or 601-359-2081.

5. 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 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.

6. A public hearing on this SPA will not be held.

State of Mississippi

DESCRIPTIONS OF LIMITATIONS AS TO AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

12a. **Physician Administered Drugs and Implantable Drug System Devices:**

The Division of Medicaid defines Physician Administered Drugs and Implantable Drug System Devices as any covered diagnostic or therapeutic radiopharmaceutical, contrast imaging agent, drug, biological or implantable drug system device that is administered in a clinically appropriate manner to a beneficiary by a Mississippi Medicaid provider other than a pharmacy provider. Physician Administered Drugs are not counted toward the monthly prescription limit.

The Division of Medicaid covers Physician Administered Drugs and Implantable Drug System Devices under the medical benefit as listed on the Physician's Fee Schedule located at www.medicaid.ms.gov/FeeScheduleLists.aspx.

The Division of Medicaid covers certain Physician Administered Drugs, referred to as Clinician Administered Drugs and Implantable Drug System Devices (CADD), under the pharmacy benefit as listed on the CADD Drug List located at https://medicaid.ms.gov/wp-content/uploads/2018/06/CADD.pdf.

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 are defined by the Division of Medicaid, updated no less than monthly and located at https://medicaid.ms.gov/providers/pharmacy/pharmacy-reimbursement/. Ingredient cost is defined as the lesser of:
   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 plus a professional dispensing fee of $61.14.
      b. Drugs purchased outside of the 340B program by covered entities – Ingredient cost is defined as the lesser of:
         1) WAC plus zero percent (0%) plus a professional dispensing fee of $61.14, or
         2) A rate set by the Division of Medicaid's rate-setting vendor plus a professional dispensing fee of $61.14 when no WAC is available, or
         3) The provider's usual and customary charge.
   2. For a non-340B covered entity:
      a. WAC plus zero percent (0%) plus a professional dispensing fee of $61.14, or
      b. A rate set by the Division of Medicaid's rate-setting vendor plus a professional dispensing fee of $61.14 when no WAC is available, or
      c. 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 based on AAC which is defined as the lesser of:
   1. NADAC plus a professional dispensing fee of $11.29, or
   2. WAC plus zero percent (0%) plus a professional dispensing fee of $11.29 when no NADAC is available, or
   3. A rate set by the Division of Medicaid's rate-setting vendor plus a professional dispensing fee of $11.29 when no NADAC or WAC are available, or
   4. The provider's usual and customary charge.

H. Clotting Factor from Specialty Pharmacies, Hemophilia Treatment Centers (HTCs), or Centers of Excellence – Ingredient cost defined as:
   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 clotting factor product plus a professional dispensing fee of $0.02 per Unit.
      b. Drugs purchased outside of the 340B program by covered entities – Ingredient cost which is defined as the lesser of:
         1) WAC minus ten percent (10%) plus a professional dispensing fee of $0.02 per Unit, or
         2) A rate set by the Division of Medicaid's rate-setting vendor plus a professional dispensing fee of $0.02 when no WAC is available, or
         3) The provider's usual and customary charge.
   2. For a non-340B covered entity – Ingredient cost is defined as the lesser of:
      a. WAC minus ten percent (10%) plus a professional dispensing fee of $0.02 per Unit, or
      b. A rate set by the Division of Medicaid's rate-setting vendor plus a professional dispensing fee of $0.02 when no WAC is available, or
      c. The provider's usual and customary charge.

I. Physician Administered Drugs as defined in Attachment 3.1-A, Exhibit 12a, Page 5 and reimbursed:
   1. Under the pharmacy benefit as described in A - H above.
   2. Under the medical benefit as described in Attachment 4.19-B, pages 12a.3-12a.4.

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.

Physician Administered Drugs and Implantable Drug System Devices Under the Medical Benefit

Drugs and Biologicals

Drugs and Biologicals are reimbursed at the lesser of the provider's usual and customary charge or a fee from a statewide uniform fee schedule updated quarterly (July 1, October 1, January 1, April 1) of each year and effective for services provided on or after that date. The statewide uniform fee schedule will be calculated using the Quarterly Medicare Part B Drug Average Sales Price (ASP) plus six percent (6%) in effect quarterly (July 1, October 1, January 1, April 1) of each year.

1) If there is no ASP a fee will be calculated at one hundred percent (100%) of the current April Medicare Addendum B Outpatient Prospective Payment System (OPPS) Fee Schedule updated July 1 of each year and effective for services provided on or after that date.

2) If there is no ASP or Medicare Addendum B OPPS Fee Schedule a fee will be calculated using RED BOOK™ in effect on January 1 of each year and updated July 1 of each year and effective for services provided on or after that date.

3) If there is no (a) ASP, Medicare Addendum B OPPS Fee or RED BOOK™ fee or (b) when it is determined, based on documentation, that a drug or biological fee is insufficient for the Mississippi Medicaid population or could result in a potential access issue, the price will be one hundred percent (100%) of the current invoice submitted by the provider including:

(1) A matching National Drug Code (NDC) as the product provided, and

(2) Medical documentation of the dosage administered.

Implantable Drug System Devices

Implantable drug system devices are reimbursed at the lesser of the provider's usual and customary charge or a fee from a statewide uniform fee schedule updated quarterly (July 1, October 1, January 1, April 1) of each year and effective for services provided on or after that date. The statewide uniform fee schedule will be calculated using the Quarterly Medicare Part B Drug ASP plus six percent (6%) in effect quarterly (July 1, October 1, January 1, April 1) of each year.

1) If there is no ASP a fee will be calculated at one hundred percent (100%) of the current April Medicare Addendum B OPPS Fee Schedule updated July 1 of each year and effective for services provided on or after that date.

2) If there is no ASP or Medicare Addendum B OPPS Fee Schedule a fee will be calculated using RED BOOK™ in effect on January 1 of each year and updated July 1 of each year and effective for services provided on or after that date.

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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 are defined by the Division of Medicaid, updated no less than monthly and located at https://medicaid.ms.gov/providers/pharmacy/pharmacy-reimbursement/. ~~not dispensed by a retail community pharmacy and dispensed primarily through the mail~~ Ingredient cost is defined as the lesser of:

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 plus a professional dispensing fee of $61.14.

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2) If there is no ASP or Medicare Addendum B OPPS Fee Schedule a fee will be calculated using RED BOOK™ in effect on January 1 of each year and updated July 1 of each year and effective for services provided on or after that date.