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State/Territory Name: District of Columbia

State Plan Amendment (SPA) #: 17-002

This file contains the following documents in the order listed:

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
150 S. Independence Mall West
Suite 216, The Public Ledger Building
Philadelphia, Pennsylvania 19106-3499

Region III/Division of Medicaid and Children's Health Operations
SWIFT # 062620174052

July 6, 2017

Claudia Schlosberg, J.D.
Senior Deputy Director/State Medicaid Director
Department of Health Care Finance
441 4th Street, N.W., Suite 900 South
Washington, D.C. 20001

Dear Ms. Schlosberg:

I am writing to inform you that we have reviewed the District of Columbia's State Plan Amendment (SPA) #17-002 entitled, Reimbursement of Covered Outpatient Drugs. This SPA proposes to bring the District of Columbia into compliance with the reimbursement requirements of the Covered Outpatient Drug final rule with comment period (CMS-2345-FC) (81 FR 5170). Specifically, the District of Columbia proposes shifting from Estimated Acquisition Cost (EAC) to Actual Acquisition Cost (AAC) by using the National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee of $11.15. In addition, the SPA addresses coverage policies of covered outpatient drugs to clarify the scope of services available for individuals eligible for State Plan PCA services, under the SPA recently approved by CMS, SPA #15-007

We are pleased to inform you that, after extensive review, this amendment is approved; its effective date is May 6, 2017. A copy of the approved SPA pages and signed CMS-179 form are included under this cover.

If you have any further questions regarding this SPA, please contact LCDR Frankeena Wright at 215-861-4754 or by email at Frankeena.Wright@cms.hhs.gov.

Sincerely,

[redacted]

Francis T. McCullough
Associate Regional Administrator

cc: Alice Weiss, DHC
Sabrina Tillman Boyd, CMS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER: **17-002**	2. STATE District of Columbia
	3. PROGRAM IDENTIFICATION: Title XIX of the Social Security Act	
TO: Regional Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services	4. PROPOSED EFFECTIVE DATE May 6, 2017	

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION Section 1927 of the Social Security Act (42 U.S.C. 1396r–8); 42 CFR Part 447	7. FEDERAL BUDGET IMPACT a. FFY 17 $ (1,876,948.00) b. FFY 18 $ (4,504,314.00)
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Supplement 1 to Attachment 3.1-A , pp. 18 – 19 Supplement 1 to Attachment 3.1-B, pp. 17 – 18 Attachment 4.19B, pp. 2 – 4	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)* Supplement 1 to Attachment 3.1-A , pp. 18 – 19 Supplement 1 to Attachment 3.1-B, pp. 17 – 18 Attachment 4.19B, pp. 2 – 4

10. SUBJECT OF AMENDMENT:

Reimbursement of Covered Outpatient Drugs

11. GOVERNOR'S REVIEW *(Check One)*
- ☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
- ☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
- ☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
- ☒ OTHER, AS SPECIFIED:
  Resolution Number: 21-0488

12. SIGNATURE OF STATE AGENCY OFFICIAL [redacted]	16. RETURN TO Claudia Schlosberg, J.D. Senior Deputy Director/Medicaid Director Department of Health Care Finance 441 4th Street, NW, 9th Floor, South Washington, DC 20001
13. TYPED NAME Claudia Schlosberg J.D.	
14. TITLE Senior Deputy Director/Medicaid Director	
15. DATE SUBMITTED April 03, 2017	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED April 3, 2017	18. DATE APPROVED June 28, 2017

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL May 6, 2017	20. SIGNATURE OF REGIONAL OFFICIAL [redacted]
21. TYPED NAME Francis T. McCullough	22. TITLE Associate Regional Administrator

23. REMARKS

12. Prescribed Drugs, Dentures and Prosthetic Devices and Eyeglasses

A. Prescribed Drugs

1) a. Prescribed drugs are limited to legend drugs approved as safe and effective by the Federal Food and Drug Administration.

b. The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit – Part D:

i. ☒ Select agents when used for anorexia, weight loss, weight gain (Megestrol).

ii. ☐ Agents when used to promote fertility.

iii. ☐ Agents when used for symptomatic relief cough and colds.

iv. ☒ Select prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations (e.g., single agent Vitamin B1, Vitamin B6, Vitamin B12, Vitamin D, folic acid products, geriatric vitamins).

v. ☒ Select nonprescription drugs (e.g., oral analgesics with a single active ingredient, antacids, family planning drugs, senna extract, single ingredient antihistamine medications).

vi. ☐ Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

c. i. The District of Columbia will provide reimbursement for covered outpatient drugs consistent with prior authorization and other requirements under Section 1927 of the Social Security Act.

ii. Prenatal vitamins and fluoride preparations will be covered as required under Section 1927 of the Social Security Act.

2) The Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

3) Agents when used for the treatment of sexual or erectile dysfunction are excluded from coverage through the Outpatient Pharmacy Program, except for limited medical uses as required by federal law.

4) a. Investigational drugs shall be excluded from coverage.

b. Over-the-counter drugs provided by nursing home pharmacies are excluded from coverage through the Outpatient Pharmacy Program.

c. The state will cover agents when used for cosmetic purposes or hair growth only when the state has determined that use to be medically necessary.

5) The District provides coverage for other drugs or products used for mitigating disease in the event of a public health emergency.

6) Supplemental Rebate Program:
The District is in compliance with section 1927 of the Social Security Act. The District has the

following policies for the Supplemental Rebate Program for the Medicaid population:

a. The "Supplemental Drug Rebate Agreement" between the participating states, Magellan Medicaid Administration, and the participating manufacturers, has been submitted to CMS and authorized by CMS effective October 1, 2013.

b. CMS has authorized the District of Columbia to enter into the National Medicaid Pooling Initiative (NMPI) for outpatient drugs provided to Medicaid beneficiaries. The Supplemental Drug Rebate Agreement authorizes the District to enter into new or renewal agreements with pharmaceutical manufacturers for outpatient drugs provided to Medicaid beneficiaries.

c. Supplemental rebates received by the District in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national drug rebate agreement.

d. Manufacturers who do not participate in the supplemental rebate program will continue to have their drugs made available to Medicaid participants through either the preferred drug list or the prior authorization process.

12. Prescribed Drugs, Dentures and Prosthetic Devices and Eyeglasses

A. Prescribed Drugs

1) a. Prescribed drugs are limited to legend drugs approved as safe and effective by the Federal Food and Drug Administration.

b. The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit – Part D:

i. ☒ Select agents when used for anorexia, weight loss, weight gain (Megestrol).

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iii. ☐ Agents when used for symptomatic relief cough and colds.

iv. ☒ Select prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations (e.g., single agent Vitamin B1, Vitamin B6, Vitamin B12, Vitamin D, folic acid products, geriatric vitamins).

v. ☒ Select nonprescription drugs (e.g., oral analgesics with a single active ingredient, antacids, family planning drugs, senna extract, single ingredient antihistamine medications).

vi. ☐ Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

c. i. The District of Columbia will provide reimbursement for covered outpatient drugs consistent with prior authorization and other requirements under Section 1927 of the Social Security Act.

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b. Over-the-counter drugs provided by nursing home pharmacies are excluded from coverage through the Outpatient Pharmacy Program.

c. The state will cover agents when used for cosmetic purposes or hair growth only when the state has determined that use to be medically necessary.

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6) Supplemental Rebate Program:

The District is in compliance with section 1927 of the Social Security Act. The District has the following policies for the Supplemental Rebate Program for the Medicaid population:

a. The "Supplemental Drug Rebate Agreement" between the participating states, Magellan Medicaid Administration, and the participating manufacturers, has been submitted to CMS and authorized by CMS effective October 1, 2013.

b. CMS has authorized the District of Columbia to enter into the National Medicaid Pooling Initiative (NMPI) for outpatient drugs provided to Medicaid beneficiaries. The Supplemental Drug Rebate Agreement authorizes the District to enter into new or renewal agreements with pharmaceutical manufacturers for outpatient drugs provided to Medicaid beneficiaries.

c. Supplemental rebates received by the District in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national drug rebate agreement.

d. Manufacturers who do not participate in the supplemental rebate program will continue to have their drugs made available to Medicaid participants through either the preferred drug list or the prior authorization process.

b. Payments are not in excess of reasonable charges consistent with efficiency, economy, and quality of care keeping with the requirement of Section 1902(a)(30) of the Act.

4. The rates of payment are included in the fee structures for types of care or services (other than inpatient hospital services) listed in Section 1905 (a) of the Act. The rates are established and included in the program under the plan as follows:

a. Non-State-operated services will be reimbursed at rates established by the State Agency and included as a part of the "Condition of Participation" for non-State providers of services under this State Plan.

b. State-operated services will be reimbursed at rates established by the State and subject to reevaluation, and adjustment where indicated by the State Agency at least once a year. These services include emergency ambulance service provided by the D.C. Fire Department. These rates are designed to meet as reasonably as practicable, but not to exceed the actual cost of the services provided, and are charged to those individuals who are required to pay for such services.

5. Drugs

a. The Medicaid agency restricts payment to only those drugs that are approved by the U.S. Federal Drug Administration (FDA) for safety and effectiveness and supplied from manufacturers that have signed a national rebate agreement, or have an approved existing agreement, as specified in Section 1927(a).

b. Methods established for determining prescription reimbursement are as follows:

i. The reimbursement methods for brand name drugs and multiple source drugs, set forth under sections 5.c or 5.d of this Attachment, shall apply to the following claims, as appropriate:

A. Pharmacy claims for retail pharmacy providers;

B. Specialty drugs primarily dispensed through the mail;

C. Non-retail community pharmacies (e.g., institutional or long-term care pharmacy when not included as part of an inpatient stay);

D. Clotting factors from Specialty Pharmacies Hemophilia Treatment Centers, Centers of Excellence;

c. Payment for the cost of brand name drugs shall be the lesser of:

i. The pharmacies' usual and customary charges to the general public; or

ii. The actual acquisition cost (AAC) plus a professional dispensing fee as established in 5.e. The AAC shall be defined as DHCF's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers. The AAC shall be based on the lesser of the National Average Acquisition Cost (NADAC) or the Wholesale Acquisition Cost plus zero percent (0%).

d. Payment for the cost of multiple source drugs shall be the lesser of:

i. The Federal Upper Limit (FUL) of the drug for multiple source drugs plus a professional dispensing fee as described in 5.e;

ii. NADAC plus a professional dispensing fee as described in 5.e;

iii. WAC plus zero percent (0%) plus a professional dispensing fee as described in 5.e;

iii. The pharmacy's usual and customary charges to the general public; or

iv. The District Maximum Allowable Cost (DMAC) plus a professional dispensing fee as described in 5.e. The DMAC shall be established and applied as follows:

A. A DMAC may be established for any drug for which two or more A-rated therapeutically equivalent, source drugs with a significant cost difference. The DMAC will be determined taking into account drug price status (non- rebatable, rebatable), marketplace status (obsolete, regional availability), equivalency rating (A-rated), and relative comparable pricing. Other factors considered are clinical indications of generic substitution, utilization, and availability in the marketplace.

B. The DMAC rate shall be applied to multiple source drugs as follows:

I. Multiple drug pricing resources are utilized to determine the pricing for multiple source drugs, applying the necessary multipliers to ensure reasonable access by

providers to the drug at or below the determined pricing benchmark;

II. The resources used to determine DMAC are maintained by a vendor under contract with DHCF, and include but are not limited to pharmacy providers, wholesalers, drug file vendors such as First Data Bank, and pharmaceutical manufacturers, or any current equivalent pricing benchmark;

C. DHCF shall supplement the CMS listing for DMAC pricing described in 5.d.iv by adding drugs and their prices which meet the following requirements:

I. The formulation of the drug approved by the U.S. Food and Drug Administration (FDA) has been evaluated as therapeutically equivalent in the most current edition of its publication, Approved Drug Products with Therapeutic Equivalence Evaluations (including supplements or in successor publications); and

II. At least two (2) suppliers list the drug (which has been classified by the FDA as category "A" in its publication, Approved Drug Products with Therapeutic Equivalence Evaluations, including supplements or in successor publications) based on listing of drugs which are locally available.

e. The professional dispensing fee rate is $11.15 per prescription.

f. For drugs purchased through the Federal Public Health Service's 340B Drug Pricing Program, the submitted ingredient cost shall be the 340B acquisition cost. 340B covered entity pharmacies that include Medicaid claims in the 340B Drug Pricing Program will be reimbursed at their 340B actual acquisition cost, but no more than the 340B ceiling price, plus the established professional dispensing fee. Drugs purchased outside of the 340B program will be reimbursed using the lesser of methodology described in Section 5.c or 5.d, plus the established professional dispensing fee. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered.

g. Drugs acquired via the Federal Supply Schedule (FSS) will be reimbursed at the FSS actual acquisition cost, plus the established professional dispensing fee.

h. Drugs acquired at Nominal Price will be reimbursed at their actual acquisition cost, plus the established professional dispensing fee.

i. Effective May 1, 2016, physician-administered drugs shall be reimbursed at eighty percent (80%) of the Medicare fee schedule, with the exception of physician-administered chemotherapy drugs which shall be reimbursed at one hundred percent (100%) of the Medicare fee schedule. Rates will be updated annually pursuant to the Medicare fee schedule, and will be published on DHCF's website at www.dc-medicaid.com.

j. For physician administered drugs purchased through the Federal Public Health Service's 340B Drug Pricing Program, reimbursement shall be the 340B actual acquisition cost, but no more than the 340B ceiling price.

k. Investigational drugs shall not be Medicaid-reimbursable.

DEFINITIONS

For the purposes of Section 3 in this State Plan Amendment, the following terms and phrases shall have the meanings ascribed:

Brand – any registered trade name commonly used to identify a drug.

Container – A light resistant receptacle designed to hold a specific dosage form which is or maybe in direct contact with the item and does not interact physically or chemically with the item or adversely affect the strength, quality, or purity of the item.

Department of Health Care Finance (DHCF) – The executive department responsible for administering the Medicaid program within the District of Columbia.

Federal Supply Schedule (FSS) - a multiple award, multi-year federal contract for medical equipment, supplies, pharmaceutical, or service programs that is available for use by federal government agencies that complies with all federal contract laws and regulations. Pricing is negotiated based on how vendors do business with their commercial customers.

6. Physician and Specialty Services

a. For service where the procedure code falls within the Medicare (Title XVIII) fee schedule, payment will be the lesser of the Medicare rate; the actual charges to the general public; or the rate listed in DHCF's fee schedule. Effective January 1, 2011, DHCF will use the Medicare rates to determine the Medicaid rates for services on or after that date. Beginning January 1, 2011, physician and specialty services rates will be reimbursed at eighty percent (80%) of the Medicare rate. All rates will be updated annually pursuant to the Medicare fee schedule. Except as otherwise noted in the Plan, State developed fee schedule rates are the same for both governmental and private individual practitioners and the fee schedule and any annual/periodic adjustments to the fee schedule are published in www.dcmedicaid.com. Effective January 1, 2015 through September 30, 2015, the state reimburses for services provided by physicians with a primary specialty designation of family medicine, pediatric medicine or internal medicine using the enhanced rates in effect pursuant to the requirements of 42 C.F.R. § 447.400(a).

Effective January 1, 2016, the state reimburses for specified services provided by qualified physicians and advanced practice registered nurses (APRNs) with a primary specialty designation of family medicine, pediatric medicine, psychiatry, obstetrics and gynecology or internal medicine utilizing Evaluation and Management (E&M) Codes and Vaccine Administration Codes authorized in Supplement 3 to Attachment 4.19B. Both physicians and APRNs shall deliver services that are predicated upon their scopes of practice and are in accordance with rules and regulations promulgated by the District of Columbia Health Occupations Board.

b. Effective January 1, 2011, for services where the procedure code does not fall within the Medicare fee schedule, DHCF will apply the lowest of the following: (1) usual and customary charges; (2) rates paid by the surrounding states of Maryland and Virginia; or (3) rates set by national benchmark compendiums when available.