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State/Territory Name: District of Columbia

State Plan Amendment (SPA)#: DC-23-0016

This file contains the following document in the order listed:

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

Center for Medicaid and CHIP Services

Medicaid Benefits and Health Programs Group

March 14, 2024

Melisa Byrd
Senior Deputy Director/Medicaid Director
Department of Health Care Finance
441 4th Street, NW, 9th Floor, South
Washington, DC 20001

re: District of Columbia State Plan Amendment (SPA) 23-0016

Dear Director Byrd:

The CMS Division of Pharmacy team has reviewed District of Columbia's State Plan Amendment (SPA) 23-0016, received in the CMS Division of Program Operations on December 22, 2023. This amendment proposes to allow the District:

- to update the state's excluded drug listing,
- to provide coverage for select agents for the treatment of infertility,
- enter in Outcome-based arrangements with manufacturers, and
- to increase flexibility to improve access to prescription and over-the-counter drugs.

Based on the information provided and consistent with the regulations at 42 CFR 447.20, we are pleased to inform you DC-23-0016 is approved with an effective date of January 1, 2024. Our review was limited to the material necessary to evaluate the SPA under applicable federal laws and regulations.

We are attaching a copy of the signed CMS-179 form, as well as the pages approved for incorporation into District of Columbia's state plan. If you have any questions regarding this state plan amendment, please contact Desiree Elekwa Izuakor at 667-290-9590 or desiree.elekwaizuakor@cms.hhs.gov.

Sincerely,

[redacted]

Cynthia R. Denemark, R.Ph.
Director, Division of Pharmacy

cc: Mario Ramsey, Department of Health Care Finance
Charlene Fairfax, Department of Health Care Finance
Terri Fraser, Washington, DC Lead, CMS

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER: **DC 23-0016**

2. STATE: **District of Columbia**

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT

TO: CENTER DIRECTOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE:
January 1, 2024

5. FEDERAL STATUTE/REGULATION CITATION:
42 CFR 440.120

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars):
a. FFY 2024 $818,210
b. FFY 2025 $282,374

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Supplement 1 to Attachment 3.1-A Page 18
Supplement 1 to Attachment 3.1-B Page 17

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Supplement 1 to Attachment 3.1-A Page 18
Supplement 1 to Attachment 3.1-B Page 17

9. SUBJECT OF AMENDMENT:

To provide coverage of select drugs for the treatment of infertility; to provide the District with the authority to enter into value-based arrangements with drug manufacturers; and, to increase flexibility to improve access to prescription and over-the-counter drugs.

10. 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:
D.C. Act: 22-434

11. [redacted]ENCY OFFICIAL

12. TYPED NAME
Melisa Byrd

13. TITLE
Senior Deputy Director/Medicaid Director

14. DATE SUBMITTED
12/22/2023

15. RETURN TO

Melisa Byrd
Senior Deputy Director/Medicaid Director
Department of Health Care Finance
441 4th Street, NW, 9th Floor, South
Washington, DC 20001

FOR CMS USE ONLY

16. DATE RECEIVED
12/22/2023

17. DATE APPROVED
03/14/2024

PLAN APPROVED – ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
01/01/2024

19. 1[redacted]AL

20. TYPED NAME OF APPROVING OFFICIAL
Cynthia R. Denemark, R.Ph

21. TITLE OF APPROVING OFFICIAL
Director, Division of Pharmacy

22. 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 as listed in the District's pharmacy provider manual.

ii. ☒Select agents when used to promote fertility as listed in the District's pharmacy provider manual.

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

iv. ☒Select prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations as listed in the District's pharmacy provider manual

v. ☒Select nonprescription drugs as listed in the District's pharmacy provider manual.

vi. ☐Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated test 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 beneficiaries 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.

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 to excess of those required under the national drug rebate agreement will be shared with the federal government on the same percentage basis 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.

e. As specified in Section 1927(b)(3)(D) of the Act, notwithstanding any other provisions of law, rebate information disclosed by a manufacturer shall not be disclosed by the District for purposes other than rebate invoicing and verification.

f. CMS has authorized the District of Columbia to enter into outcomes-based contract arrangements with drug manufacturers for drugs provided to Medicaid beneficiaries. These contracts will be executed on the contract template titled "Outcomes-Based Supplemental Rebate Agreement" submitted to CMS and authorized for use beginning January 1, 2024.

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