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State Name: Virginia

State Plan Amendment (SPA) #: 17-011

This file contains the following documents in the order listed:

- 1) Approval Letters
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 3) Approved SPA Page

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 #081120174036

September 7, 2017

Cynthia B. Jones, Director Department of Medical Assistance Services 600 East Broad Street, Suite 1300 Richmond, VA 23219

Dear Ms. Jones:

The Centers for Medicare & Medicaid Services (CMS) has reviewed Virginia's State Plan Amendment (SPA) 17-011, Supplemental Drug Rebates and Managed Care Organizations. The Pharmacy Team at CMS approved this SPA on September 6, 2017 and you were duly notified. This SPA proposes to include the terms upon which Virginia will collect supplemental rebates from drug manufacturers on those drugs dispensed to Medicaid Managed Care Organizations' (MCO) enrollees.

This SPA is acceptable. Therefore, we are approving SPA 17-011 with an effective date of July 1, 2017. Enclosed is the approved SPA page and signed CMS-179 form.

If you have further questions about this SPA, please contact Margaret Kosherzenko of my staff at 215-861-4288.

Sincerely,

/S/

Francis McCullough Associate Regional Administrator

Enclosures

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

Disabled and Elderly Health Programs Group

September 6, 2017

Ms. Cynthia B. Jones Director Department of Medical Assistance Services 600 Broad Street, #1300 Richmond, VA 23219

Dear Ms. Jones:

We have reviewed Virginia's State Plan Amendment (SPA) 17-011, received in the Philadelphia Regional Office on July 20, 2017. Virginia's amendment proposes to include the terms upon which the state will collect supplemental rebates from drug manufacturers on those drugs dispensed to Medicaid Managed Care Organizations (MCO) enrollees. We are pleased to inform you that the amendment is approved with an effective date of July 1, 2017.

Based on the information provided, we believe this amendment is consistent with the objectives of the Medicaid program, it is designed to increase the efficiency and economy of the Medicaid program and benefits Medicaid beneficiaries. Approval of the Virginia SPA 17-011 extends only to Supplemental Drug Rebates and Managed Care Organizations to the Plan for Medical Assistance for the Commonwealth of Virginia. If changes are subsequently made to the supplemental rebate agreement or its attachments, a new SPA and any required documents should be submitted to CMS for review and authorization.

A copy of the signed CMS-179 form, as well as the pages approved for incorporation into the Virginia state plan will be forwarded by the Philadelphia Regional Office.

If you have any questions regarding this amendment, please contact Yolonda Williams at (410) 786-6618 or yolonda.williams@cms.hhs.gov.

Sincerely,

/s/

John M. Coster, Ph.D., R.Ph. Director Division of Pharmacy

CC: Francis T. McCullough, ARA, CMS, Philadelphia Regional Office

CENTEND FOR MEDICANE & MEDICAND CENTRICES				
TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	1. TRANSMITTAL NUMBER 2. STATE Virginia			
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)			
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE July 1, 2017			
5. TYPE OF PLAN MATERIAL (Check One)				
☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONS				
	ENDMENT (Separate transmittal for each amendment)			
6. FEDERAL STATUTE/REGULATION CITATION	7. FEDERAL BUDGET IMPACT a. FFY 2011 \$			
42 CFR Part 440	b. FFY 3018 \$0			
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION			
Attachment 3.1 - A &B, page 26.1	OR ATTACHMENT (If Applicable)			
Attachment 3.1 - A &B, page 20.1	Same page			
-				
10. SUBJECT OF AMENDMENT				
	Organizations			
Supplemental Drug Rebates and Managed Care (Jiganizations			
. GOVERNOR'S REVIEW (Check One)				
GOVERNOR'S OFFICE REPORTED NO COMMENT	☑ OTHER, AS SPECIFIED			
COMMENTS OF GOVERNOR'S OFFICE ENCLOSED	Secretary of Health and Human Resources			
NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL				
12. SIGNATURE OF STATE AGENCY OFFICIAL	16. RETURN TO			
/S/				
13. TYPED NAME Cynthia B. Jones	Dept. of Medical Assistance Services			
14. TITLE	600 East Broad Street, #1300			
Director	Richmond VA 23219			
15. DATE SUBMITTED	Attn: Regulatory Coordinator			
FOR REGIONAL O	FFICE USE ONLY			
17, DATE RECEIVED	18 DATE APPROVED			
July 20, 2017	September 6, 2017			
PLAN APPROVED - O				
19. EFFECTIVE DATE OF APPROVED MATERIAL July 1, 2017	20. SIGNATURE OF REGIONAL OFFICIAL /S/			
21. TYPED NAME	22. TITLE			
Francis McCullough	ssociate Regional Administrator			
23. REMARKS				
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Revision: HFCA-PM-91-4

August, 1991

(BPD)

Attachment 3.1- A&B
Supplement 1
Page 26.1
OMB No. 0938-

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State of VIRGINIA

AMOUNT, DURATION, AND SCOPE OF MEDICAL
AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY
and MEDICALLY NEEDY

- e. State supplemental rebates. The Department has the authority to seek supplemental rebates from pharmaceutical manufacturers. In addition to collecting supplemental rebates for fee-for-service claims, the Department may, at its option, also collect supplemental rebates for Medicaid member utilization through MCOs under an agreement. The contract regarding supplemental rebates shall exist between the manufacturer and the Commonwealth. Rebate agreements between the Commonwealth and a pharmaceutical manufacturer shall be separate from the federal rebates and in compliance with federal law, §§ 1927(a)(1) and 1927(a)(4) of the Social Security Act (Act). All rebates collected on behalf of the Commonwealth shall be collected for the sole benefit of the state share of the costs. One hundred percent of the supplemental rebates collected on behalf of the state shall be remitted to the state. Supplemental drug rebates received by the Commonwealth 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.
- f. Pursuant to 42 U.S.C. § 1396r-8(b)(3)(D), information disclosed to the Department or to the Committee by a pharmaceutical manufacturer or wholesaler which discloses the identity of a specific manufacturer or wholesaler and the pricing information regarding the drugs by such manufacturer or wholesaler is confidential and shall not be subject to the disclosure requirements of the Virginia Freedom of Information Act (§2.2-3700 et seq. of the Code of Virginia).
- g. Appeals for denials of prior authorization shall be addressed pursuant to 12VAC30-110, Part I, Client Appeals.
- 8. Coverage of home infusion therapy. This service shall be covered consistent with the limits and requirements set out within home health services (12 VAC 30-50-160). Multiple applications of the same therapy (e.g. two antibiotics on the same day) shall be covered under one service day rate of reimbursement. Multiple applications of different therapies (e.g. chemotherapy, hydration, and pain management on the same day) shall be covered under a full service day rate methodology as provided in pharmacy services reimbursement.
- 12a. Reserved
- 12b. Dentures.
 - A. Provided only as a result of EPSDT and subject to medical necessity and preauthorization requirements specified under Dental Services.

TN No. 17-011	Approval Date <u>September</u> 6, 2017	Effective Date	07-01-17
Supersedes	-		
TN No. <u>05-03</u>			