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State Name: Virginia

State Plan Amendment (SPA) #: 19-015

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) Pharmacy Approval Letter
- 3) CMS-179
- 4) Approved SPA Page

DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services Center for Medicaid and CHIP Services 801 Market Street, Suite 9400 Philadelphia, Pennsylvania 19107



Center for Medicaid and CHIP Services

SWIFT #120420194009

January 7, 2020

Karen Kimsey, Director Virginia Department of Medical Assistance Services 600 East Broad Street, Suite 1300 Richmond, VA 23219

Dear Ms. Kimsey:

The Centers for Medicare & Medicaid Services (CMS) has reviewed Virginia's State Plan Amendment (SPA) 19-015, Update to Supplemental Drug Rebate Agreement. CMS approved this SPA on January 3, 2020 and you were duly notified. This SPA proposes to amend the terms for which Virginia will collect supplemental rebates from drug manufacturers.

This SPA is acceptable. Therefore, we are approving SPA 19-015 with an effective date of October 1, 2019. 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 T. McCullough Deputy Group Director Financial Management Group



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

January 3, 2020

Ms. Karen Kimsey, Director Department of Medical Assistance Services 600 East Broad Street, #1300 Richmond, Virginia 23219

Dear Ms. Kimsey:

We have reviewed Virginia's State Plan Amendment (SPA) 19-0015, Update to Supplemental Drug Rebate Agreement, received in the Philadelphia Regional Operations Group on November 1, 2019. This SPA proposes to amend the terms for which the state will collect supplemental rebates from drug manufacturers for the effective date of October 1, 2019.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 19-0015 is approved with an effective date of October 1, 2019. Approval of the Virginia SPA 19-0015 extends only to Supplemental Drug Rebates. 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 Commonwealth of Virginia's state plan will be forwarded by the Philadelphia Regional Operations Group.

If you have any questions regarding this amendment, please contact Whitney Swears at (410) 786-5445 or <u>Whitney.Swears@cms.hhs.gov</u>.

Sincerely,

/s/

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

cc: Daniel Carey, M.D., Secretary of Health and Human Resources
 Emily McClellan, Regulatory Supervisor, Department of Medical Assistance Services
 Sabrina Tillman-Boyd, Branch East, Regional Operations Group
 Margaret Kosherzenko, Philadelphia Regional Operations Group

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 DR: CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER 2. STATE 1 9 0 1 5 Virginia 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 10/1/2019
5. TYPE OF PLAN MATERIAL (Check One)	
NEW STATE PLAN AMENDMENT TO BE CONS	IDERED AS NEW PLAN
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AME	NDMENT (Separate transmittal for each amendment)
6. FEDERAL STATUTE/REGULATION CITATION 42 CFR Part 440	7. FEDERAL BUDGET IMPACT a. FFY 2019 \$ -0- b. FFY 2020 \$ -0-
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)
3.1 A&B, Supplement 1, page 26.1 - revised	Same as box 8
10. SUBJECT OF AMENDMENT	
Update to Supplemental Drug Rebate Agreement	
 VERNOR'S REVIEW (Check One) GOVERNOR'S OFFICE REPORTED NO COMMENT²⁰¹⁹ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL SIGNATURE OF STATE AGENCY OFFICIAL 	OTHER, AS SPECIFIED Secretary of Health and Human Resources 16. RETURN TO
12. SIGNATURE OF STATE AGENCY OFFICIAL	
13. TYPED NAME Karen Kimsey 14. TITLE Director	Dept. of Medical Assistance Services 600 East Broad Street, #1300 Richmond VA 23219
15. DATE SUBMITTED 10-24-19	Attn: Regulatory Coordinator
FOR REGIONAL OF	
17. DATE RECEIVED December 12, 2019	18. DATE APPROVED January 3, 2020
PLAN APPROVED - ON	
19. EFFECTIVE DATE OF APPROVED MATERIAL 2 October 1, 2019 2	20. SIGNATURE OF REGIONAL OFFICIAL /S/
2~ 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	22. TITLE
	Deputy Group Director Financial Management Group
23. REMARKS	

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. 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. Supplemental rebate agreements 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
- 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.
- 12b. Dentures.
 - A. Provided only as a result of EPSDT and subject to medical necessity and preauthorization requirements specified under Dental Services.