

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

February 14, 2022

Ms. Maureen Corcoran
State Medicaid Director
Ohio Department of Medicaid
P.O. Box 182709
Columbus, Ohio 43218

Dear Ms. Corcoran,

The CMS Division of Pharmacy team has reviewed Ohio's State Plan Amendment (SPA) 21-0033 received in the CMS Medicaid & CHIP Operations Group on November 29, 2021. This SPA approves a template that will authorize the state to enter in Value-Based Purchasing (VBP) rebate agreements with drug manufacturers for drugs provided under the Medicaid program.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 21-0033 is approved with an effective date of December 1, 2021. We are attaching a copy of the signed, revised CMS-179 form, as well as the pages approved for incorporation into Ohio's state plan.



If you have any questions regarding this amendment, please contact Terry Simananda at (410) 786-8144 or terry.simananda@cms.hhs.gov.

Sincerely,

A solid black rectangular box redacting the signature of John M. Coster.

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

cc: Rebecca Jackson, State Plan Team, Ohio Department of Medicaid
Gregory Niehoff, State Plan Team, Ohio Department of Medicaid
Christine Davidson, Ohio Medicaid State Lead, CMS

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL		1. TRANSMITTAL NUMBER: 21-033 Revised	2. STATE OHIO
FOR: CENTERS FOR MEDICARE AND 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 December 1, 2021	
5. TYPE OF PLAN MATERIAL (Check One):			
<input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT			
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)			
6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR 440, 441, and 447 42 U.S.C. 1396r-8		7. FEDERAL BUDGET IMPACT: a. FFY 2022 \$ 0 b. FFY 2023 \$ 0	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A, Item 12-a, Page 2		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Attachment 3.1-A, Item 12-a, Page 2 (TN 17-023)	
10. SUBJECT OF AMENDMENT: Coverage and Limitations: Prescribed drugs (Value-Based Supplemental Rebates)			
11. GOVERNOR'S REVIEW (Check One):			
<input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT		<input type="checkbox"/> OTHER, AS SPECIFIED:	
<input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED		The State Medicaid Director is the Governor's designee	
<input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATURE OF STATE AGENCY OFFICIAL: 		16. RETURN TO:	
13. TYPED NAME: MAUREEN M. CORCORAN		Greg Niehoff Ohio Department of Medicaid P.O. BOX 182709 Columbus, Ohio 43218	
14. TITLE: STATE MEDICAID DIRECTOR			
15. DATE SUBMITTED: November 29, 2021			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED: November 29, 2021		18. DATE APPROVED: February 14, 2022	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: December 1, 2021		20. SIGNATURE OF REGIONAL OFFICIAL: 	
21. TYPED NAME: John M. Coster, Ph.D., R.Ph.		22. TITLE: Director, Division of Pharmacy	
23. REMARKS:			

Instructions on Back

The state may negotiate value-based supplemental drug rebates in addition to the federal rebates provided for in Title XIX and the supplemental rebates described in Item 12-a above. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from federal rebates.

CMS has authorized the state of Ohio to enter into value-based supplemental rebate agreements with drug manufacturers for drugs provided to Medicaid beneficiaries. The “Ohio Department of Medicaid Value-Based Supplemental Rebate Agreement” submitted to CMS on November 29, 2021, has been authorized for pharmaceutical manufacturers’ new agreements and renewals.

Savings recognized from value-based supplemental rebate agreements in excess of those required under the national drug rebate agreement will be shared with the federal government on the percentage basis required by law.

Provisions related to Medicare Part D Prescription Drug Coverage

Pursuant to Section 1935(d)(1) of the Social Security Act, effective January 1, 2006, 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.

Pursuant to Sections 1927(d)(2) and 1935(d)(2) of the Social Security Act, the Medicaid agency provides coverage for the following Medicare-excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit –Part D.

The following drugs, which are subject to restriction under Section 1927(d)(2) of the Social Security Act, are covered:

- (a) agents when used for anorexia, weight loss, or weight gain
- (b) agents when used to promote fertility
- (c) agents when used for the symptomatic relief of cough and colds
- (d) prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
- (e) nonprescription drugs (only cough and cold products, antihistamines, antacids, antidiarrheals, stool softeners, laxatives, analgesics, and topical products including acne, antifungals, and corticosteroids)
- (f) 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
- (g) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.