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State/Territory Name: Alabama

State Plan Amendment (SPA) #: 19-0009

This file contains the following documents in the order listed:

- 1) RO Follow-Up Approval Letter
- 2) Pharmacy Approval Letter
- 3) CMS 179 Form
- 4) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
61 Forsyth Street S.W. Suite 4T20
Atlanta, Georgia 30303



Atlanta Regional Operations Group

December 20, 2019

Stephanie McGee Azar, Commissioner
Alabama Medicaid Agency
501 Dexter Avenue
Montgomery, AL 36103-5624

Re: Alabama State Plan Amendment 19-0009

Dear Ms. Azar:

This is to affirm approval of the above-referenced State Plan Amendment, which was submitted to the Atlanta Regional Operations Group on September 25, 2019. The state's requested effective date of July 1, 2019 has been accepted.

Enclosed for your records are:

1. a copy of the approval letter dated December 20, 2019 that was submitted to the state by John M. Coster, Director, Division of Pharmacy;
2. the original signed 179; and
3. the approved plan pages.

If you have any additional questions or need further assistance, please contact Alice Hogan at (404) 562-7432 or Alice.Hogan@cms.hhs.gov.

Sincerely,

/s/

David R. Kimble
Acting Deputy Director
Division of Medicaid Field Operations South

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

December 20, 2019

Ms. Stephanie McGee Azar
Commissioner
Alabama Medicaid Agency
501 Dexter Avenue
PO Box 5624
Montgomery, AL 36103-5624

Dear Ms. Azar:

We have reviewed Alabama State Plan Amendment (SPA) 19-0009 received in the Centers for Medicare & Medicaid Services (CMS) Atlanta Regional Operations Group on September 25, 2019. This SPA proposes to allow the Alabama Medicaid Agency to enter into value/outcome(s) based agreements with drug manufacturers for purposes of collecting additional supplemental drug rebates.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 19-0009 is approved with an effective date of July 1, 2019. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Alabama's state plan will be forwarded by the Atlanta Regional Operations Group.

If you have any questions regarding this request, please contact Justin Aplin at (410) 786-6901 or Justin.Aplin@cms.hhs.gov.

Sincerely,

/s/

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

cc: Shantrina Roberts, Director, Atlanta Regional Operations Group
Alice Hogan, Atlanta Regional Operations Group

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	1. TRANSMITTAL NUMBER: AL-19-0009	2. STATE Alabama
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
FOR: HEALTH CARE FINANCING ADMINISTRATION		
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE July 1, 2019	

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: 42 CFR Section 440.120; 42 CFR 447 Subpart I	7. FEDERAL BUDGET IMPACT: a. FFY 2019 \$0 b. FFY 2020 \$0
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1A page 5.12b	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>): Attachment 3.1A page 5.12b

10. SUBJECT OF AMENDMENT:

The primary purpose for this amendment is to obtain approval of a value/outcome(s) based agreement in order to further facilitate obtaining supplemental rebates in addition to the federal drug rebates provided for in Title XIX.

11. GOVERNOR'S REVIEW (*Check One*):

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED:
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED Governor's designee on file
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL via letter with CMS

12. SIGNATURE OF STATE AGENCY OFFICIAL: /s/	16. RETURN TO: Stephanie McGee Azar Commissioner Alabama Medicaid Agency 501 Dexter Avenue Post Office Box 5624 Montgomery, Alabama 36103-5624
13. TYPED NAME: Stephanie McGee Azar	
14. TITLE: Commissioner	
15. DATE SUBMITTED:	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 09/25/19	18. DATE APPROVED: 12/20/19
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: 07/01/19	20. SIGNATURE OF REGIONAL OFFICIAL: /s/
21. TYPED NAME: Davida R. Kimble	22. TITLE: Acting Deputy Director Division of Medicaid Field Operation South

23. REMARKS:

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

a. Prescribed Drugs – Continued

(7) Auditing by Manufacturer

The state permits manufacturers to audit utilization data as stated in (6) above. Adjustments to rebates are made to the extent that information indicates that utilization was greater or less than previously specified.

(8) Prior Approval

The state provides for response by telephone or other communication devices, e.g., fax, within 24 hours of a request for prior approval and provides for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation.

(9) Supplemental Rebate Agreements

The state is in compliance with section 1927 of the Social Security Act. The state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The state may negotiate brand and/or generic supplemental rebates and value/outcome(s)-based agreement in addition to the federal rebates provided for in Title XIX. Supplemental drug rebate agreements and value/outcome(s)-based agreement between the state and a pharmaceutical manufacturer will be separate from the federal rebates.

A supplemental drug rebate agreement between the state and a drug manufacturer for drugs provided to the Alabama Medicaid population, originally submitted to CMS on August 8, 2003, and an updated version submitted on December 1, 2015, entitled, "State of Alabama Supplemental Drug Rebate Contract," has been authorized by CMS.

A value/outcome(s)-based model agreement between the state and a drug manufacturer for drugs provided to the Alabama Medicaid population, originally submitted to CMS on July 1, 2019, entitled, "State of Alabama Value/Outcome(s) Based Agreement," has been authorized by CMS for use beginning July 1, 2019.

Supplemental rebates received by the state 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 rebate agreement.

All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

(10) Preferred Drug List

Pursuant to 42 U.S.C. section 1396r-8 the state is establishing a preferred drug list with prior authorization for drugs not included on the preferred drug list. Prior authorization will be provided with a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in emergency situations as in accordance with provisions of section 1927(d)(5) of the Social Security Act.

Prior authorization will be established for certain drug classes or particular drugs in accordance with federal law.

All drugs covered by the program irrespective of a prior authorization requirement will comply with the provisions of the national drug rebate agreement.

The state will utilize the Drug Utilization Review board to assure that in addition to pricing consideration, preferred drugs are clinically appropriate.