

Table of Contents

State/Territory Name: Alabama

State Plan Amendment (SPA)#: 20-0021

This file contains the following documents in the order listed

- 1) Approval Letter
- 2) CMS 179 Form
- 3) Approved SPA Pages

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 17, 2020

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) 20-0021 received in the Centers for Medicare & Medicaid Services (CMS) Division of Program Operations South Branch on December 1, 2020. This SPA proposes to amend the value/outcome(s) based agreement template in order to further facilitate obtaining supplemental rebates in addition to the federal drug rebates provided for in Title XIX.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 20-0021 is approved with an effective date of December 1, 2020. 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 Division of Program Operations South Branch.

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

Sincerely,

John M. Coster, Ph.D., R.Ph.
Director
Division of Pharmacy
DEHPG/CMCS/CMS

cc: Heather Vega
James G. Scott, Director
Charles Friedrich

Alabama Medicaid Agency
Division of Program Operations
Division of Program Operations South Branch

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL**

1. TRANSMITTAL NUMBER:
AL-20-0021

2. STATE
Alabama

FOR: HEALTH CARE FINANCING ADMINISTRATION

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

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
December 1, 2020

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 2020 0
b. FFY 2021 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 (*If Applicable*):
Attachment 3.1A page 5.12B

10. SUBJECT OF AMENDMENT:

The primary purpose for this amendment is amend the value/outcome(s) based agreement template 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
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

OTHER, AS SPECIFIED:
Governor's designee on file
via letter with CMS

13. TYPED NAME:
Stephanie McGee Azar

14. TITLE:
Commissioner

15. DATE SUBMITTED: 12/01/2020

16. RETURN TO:

Stephanie McGee Azar
Commissioner
Alabama Medicaid Agency
501 Dexter Avenue
Post Office Box 5624
Montgomery, Alabama 36103-5624

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 12/01/2020

18. DATE APPROVED: 12/17/2020

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
12/01/2020

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME: John Coster

22. TITLE: Director, Division of Pharmacy

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, and an updated version submitted on December 1, 2020 entitled, "State of Alabama Value/Outcome(s) Based Agreement," has been authorized by CMS.

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.