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State/Territory Name: Alabama

State Plan Amendment (SPA) #: 13-008

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



July 1, 2015

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

Re: Alabama Title XIX State Plan Amendment, Transmittal #13-008

Dear Ms. McGee Azar

This is to affirm approval of the above referenced State Plan Amendment which was submitted to the Regional Office on July 22, 2013. The State's requested effective date of October 1, 2013 has been accepted.

Enclosed for your records are:

1. a copy of the approval letter dated June 29, 2015 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 regarding this amendment, please contact Alice Hogan, State Coordinator for Alabama, at 678-749-11-03.

Sincerely,

/s/

Jackie Glaze
Associate Regional Administrator
Division of Medicaid & Children's Health Operations

Enclosure(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850



Disabled & Elderly Health Programs Group

June 29, 2015

Stephanie McGee Azar
Acting Commissioner
Alabama Medicaid Agency
501 Dexter Avenue
Post Office Box 5624
Montgomery, AL 36103-5324

Dear Ms. McGee Azar:

We have reviewed Alabama State Plan Amendment (SPA) 13-008, Prescribed Drugs, received in the Atlanta Regional Office on July 22, 2013. This amendment proposes to limit the number of outpatient pharmacy prescriptions for all recipients, with certain class exemptions, to five total drugs per month per adult recipient. Prescriptions for Medicaid eligible recipients under age 21 in the Child Health Services/Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Program and prescriptions for Medicaid eligible nursing facility residents are excluded from these limitations. This amendment also updates coverage of new drugs language; discontinues over-the-counter (OTC) drugs with exceptions; and implements a long term maintenance medication (three-month) supply benefit. Drugs dispensed in this program will be exempt from the monthly prescription limit.

Based on the information provided, we are pleased to inform you that consistent with the regulations at 42 CFR 430.20, SPA 13-008 is approved with an effective date of October 1, 2013. A copy of the signed CMS-179 form, as revised, as well as the pages approved for incorporation into the Alabama state plan will be forwarded by the Atlanta Regional Office.

If you have any questions regarding this SPA, please contact Wendy Tuttle at (410) 786-8690.

Sincerely,

/s/

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

cc: Jackie Glaze, ARA, Atlanta Regional Office
Alice Hogan, Atlanta Regional Office
Stephanie Lindsay, Administrative Procedures Officer, Alabama Medicaid Agency

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

1. TRANSMITTAL NUMBER:
AL-13-008

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
October 1, 2013

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 401, et seq.

7. FEDERAL BUDGET IMPACT:
a. FFY 14 \$ 14.94mill (savings)
b. FFY 15 \$ 14.98mill (savings)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 3.1-A, pages 5.12, 5.12a, 5.12.1, and 5.12b.1

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION
OR ATTACHMENT (*If Applicable*):

Attachment 3.1-A, pages 5.12, 5.12a, 5.12.1 and NEW

10. SUBJECT OF AMENDMENT:

The primary purpose for this amendment is to limit the number of outpatient pharmacy prescriptions for all recipients, with certain class exemptions, to five total drugs per month per adult recipient, includes exclusions; update Coverage of New Drugs language; discontinue over-the-counter (OTC) drugs with exceptions; and implement a long term maintenance medication (three month) supply benefit effective October 1, 2013.

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
Acting Commissioner
Alabama Medicaid Agency
501 Dexter Avenue
Post Office Box 5624
Montgomery, Alabama 36103-5624

13. TYPED NAME:
Stephanie McGee Azar

14. TITLE: Acting Commissioner

15. DATE SUBMITTED: 07-22-13

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 07-22-13

18. DATE APPROVED: 06/29/15

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
10/01/13

20. SIGNATURE OF REGIONAL OFFICIAL:
/s/

21. TYPED NAME:
Jackie Glaze

22. TITLE: Associate Regional Administrator
Division of Medicaid & Children Health Opns

23. REMARKS:

Approved with the following changes to item 7a and 7b as authorized by State Agency e-mails dated January 24, 2014.

Block #7 changed to read: FY14 10.3 M and FY15 10.3 M

Limitation of Services

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

12. a. **Prescribed Drugs**

Effective Date: 07/01/91

(1) **General Coverage**

Medicaid covers only drugs of participating manufacturers which have entered into and comply with an agreement under Section 1927(a) of the Act which are prescribed for a medically accepted condition.

Because of an extenuating circumstance waiver, drugs were covered from non-participating manufacturers through 3-31-91. Single source or innovator multiple source drugs classified by the Food and Drug Administration as 1A are covered if a rebate agreement has not been signed with the manufacturer if the state has made a determination that the availability of the drug is essential to the health of beneficiaries under the State Plan for Medical Assistance and the physician has requested and received prior approval in advance of its dispensing.

Effective Date: 01/01/06

- (2) Medicaid 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.

Medicaid provides coverage, for all pharmacy eligible Medicaid recipients, including full-benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit (Part D), for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses – with the exception of those covered by Part D plans as supplemental benefits through enhanced alternative coverage as provided in 42 CFR 423.104 (f) (1) (ii) (A).

Excluded Drugs

The following outpatient drugs or classes of drugs, or their medical uses are excluded from coverage or otherwise restricted, unless noted:

- (a) Agents when used for anorexia, weight loss, or weight gain except for those specified by the Alabama Medicaid Agency.
 - Orlistat is covered under prior authorization with medical justification.
- (b) Agents when used to promote fertility except for those specified by the Alabama Medicaid Agency.
 - Drugs with fertility only FDA approved indications are not covered; drugs with fertility and non-fertility FDA approved indications are covered.
- (c) Agents when used for cosmetic purposes or hair growth except for those specified by the Alabama Medicaid Agency.
 - Drugs with cosmetic only FDA approved indications are not covered; isotretinoin is covered for medical necessity with medical justification.

Effective Date: 10/01/13

- (d) Agents when used for the symptomatic relief of cough and cold.

Limitation of Services

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

12. a. **Prescribed Drugs**

- (e) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations and others as specified by the Alabama Medicaid Agency.
 - Renal vitamins and vitamin preparations used in Total Parenteral Nutrition are covered.
- (f) Non prescription drugs except for those specified by the Alabama Medicaid Agency.
 - Insulins second generation antihistamines are covered; smoking cessation products are covered for Plan First recipients and pregnant females.
- (g) 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.
- (h) Barbiturates except for generic barbiturates and for dual eligible individuals effective January 1, 2013 when used in the treatment of epilepsy, cancer or a chronic mental health disorder as Part D will cover those indications.
- (i) Benzodiazepines except for generic benzodiazepines (except estazolam) and for dual eligible individuals effective January 1, 2013 as Part D will cover all indications
- (j) Agents when used to promote smoking cessation unless authorized for pregnant females women according to the Public Health Service guidelines "Treating Tobacco Use and Dependence: 2008 Update: A Clinical Practice Guideline, or any subsequent modification of such guideline.

Limitation of Services

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

12. a. **Prescribed Drugs- Continued**

(3) **Reduction in Coverage**

The number of outpatient pharmacy prescriptions for all recipients except as specified below is limited to four brand name/five total drugs per month per adult recipient effective October 1, 2013. Anti-psychotic, anti-retroviral, and anti-epileptic agents may be paid up to ten prescriptions per month. Drugs dispensed in the Long Term Maintenance Supply program are exempt from the monthly prescription limit. Prescriptions for Medicaid eligible recipients under age 21 in the Child Health Services/Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Program and prescriptions for Medicaid eligible nursing facility residents are excluded from these limitations.

Overrides will be granted only in cases in which the prescribing physician documents medical necessity for the recipient to be switched from a product in one of the below named classes to a product within the same therapeutic class in the same calendar month. The first product must have been covered by Medicaid. State coverage may be allowed through overrides of up to ten prescriptions per month for drugs classified by American Hospital Formulary Services (AHFS) or First Data Bank (FDB) Therapeutic Class as Antineoplastic Agents, Antiarrhythmic Agents, Cardiotonic Agents, Miscellaneous Vasodilating Agents, Miscellaneous Cardiac Agents, Nitrates and Nitrites, Alpha Adrenergic Blocking Agents, Beta Adrenergic Blocking Agents, Dihydropyridines, Miscellaneous Calcium Channel Blocking Agents, Diuretics, Angiotensin-Converting Enzyme Inhibitors, Angiotensin II Receptor Antagonists, Mineralocorticoid (Aldosterone) Receptor Antagonists, Central Alpha Agonists, Direct Vasodilators, Peripheral Adrenergic Inhibitors, Miscellaneous Hypotensive Agents, Hemostatics, Calcium Replacements, Electrolyte Depleters, Immunosuppressives, Alpha Glucosidase Inhibitors, Amylinomimetics, Biguanides, Dipeptidyl Peptidase-4 Inhibitors, Incretin Mimetics, Insulins, Meglitinides, Sulfonylureas, Thiazolidinediones, and Miscellaneous Diabetic Agents.

(4) **Coverage of New Drugs**

Except for excluded drugs listed in (2) above, Medicaid covers all new drugs after FDA approval and upon notification by the manufacturer of the new drug.

(5) **Confidentiality**

Medicaid regards information disclosed by the manufacturers or wholesalers as confidential and will not disclose such information in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs as required in Section 1927 (b)(3)(D).

(6) **Reporting**

The state will report to each manufacturer not later than 60 days after the end of each calendar quarter and in a form consistent with the standard format established by the Secretary, utilization data on the total number of dosage units for each covered outpatient drug dispensed during a quarter and shall promptly transmit a copy of the report to the Secretary.

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

(11) Long Term Maintenance Supply

The State reimburses for each three month supply of Agency designated maintenance medication dispensed to recipients. A maintenance medication is an ordered/prescribed medication generally used to treat chronic conditions or illnesses and taken regularly and continuously. The following criteria apply to the three month supply:

- a. The medications will be designated by the Agency.
- b. The three month supply medications listing(s) will be available to the public on the State's website: www.medicaid.alabama.gov.
- c. The recipient will demonstrate 60 days of stable therapy prior to the State reimbursing the provider for dispensing a three month supply.
- d. An opt out program for recipients who may not be candidates for maintenance supplies will be available.