

## **Table of Contents**

**State/Territory Name: Kentucky**

**State Plan Amendment (SPA) #: 13-026**

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  
Atlanta Regional Office  
61 Forsyth Street, Suite 4T20  
Atlanta, Georgia 30303



**DIVISION OF MEDICAID & CHILDREN'S HEALTH OPERATIONS**

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January 27, 2014

Lawrence Kissner, Commissioner  
Department for Medicaid Services  
Attn: Karen Martin  
275 East Main Street, 6WA  
Frankfort, KY 40621-0001

RE: Title XIX State Plan Amendment, KY-13-026

Dear Mr. Kissner:

This is to affirm approval of the above referenced State Plan Amendment which was submitted to the Regional Office on December 10, 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 January 23, 2014 that was submitted to the State by Larry Reed, Director, Division of Pharmacy;
2. the original signed 179; and
3. the approved plan page.

If you have any additional questions regarding this amendment, please contact Melanie Benning, State Coordinator for Kentucky, at 404-562-7414.

Sincerely,

//s//

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

Enclosures



## **Disabled & Elderly Health Programs Group**

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January 23, 2014

Lawrence Kissner  
Commissioner  
Department of Medicaid Services  
275 East Main Street, 6W-A  
Frankfort, KY 40621

Dear Mr. Kissner:

We have reviewed Kentucky State Plan Amendment (SPA) 13-026, Prescribed Drugs, received in the Atlanta Regional Office on December 10, 2013. This amendment proposes to revise the National Medicaid Pooling Initiative (NMPI) Supplemental Rebate Agreement (SRA) previously submitted to CMS on March 11, 2008 to include definitions and structural changes that would provide the option of including Medicaid managed care utilization for accrual of supplemental rebates. This amendment also removes benzodiazepines, barbiturates and smoking cessation products from the list of excluded drugs to comply with the requirements of Section 2502(a) of the Affordable Care Act, and makes other technical corrections to the language in Prescribed Drugs pages of the State Plan. We are pleased to inform you that the amendment is approved effective October 1, 2013.

We believe that the Kentucky NMPI SRA continues to be consistent with the objectives of the Medicaid program. Please note that this authorization extends only to the revised SRA, attachments and schedules included in this approval packet which will replace the current SRA packet submitted to CMS on March 11, 2008. Inclusion of the managed care organization (MCO) utilization under the Kentucky NMPI SRA is optional and at the sole discretion of each member state.

If revisions are subsequently made to include MCO utilization for supplemental rebate collection or any other changes to the supplemental drug rebate agreement, attachments or schedules, all such documents should be submitted to CMS for review and approval. A separate SPA will be required if the state intends to exercise the option of including MCO utilization for supplemental rebates.

Per your approval, we made the requested changes to blocks eight and nine on the CMS-179 form. A copy of the CMS-179 form, as revised, as well as the pages approved for incorporation into the Kentucky state plan will be forwarded to you by the Atlanta Regional Office. If you have any questions regarding this SPA, please contact Wendy Tuttle at (410) 786-8690.

Sincerely,

/s/

Kim Howell  
Acting Director  
Division of Pharmacy

cc: Jackie Glaze, ARA, DMCHO, Atlanta Regional Office  
Melanie Benning, Atlanta Regional Office  
Sharley Hughes, Kentucky Department of Medicaid Services

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

1. TRANSMITTAL NUMBER:  
13-026

2. STATE  
Kentucky

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:  
Section 1927 of the SSA

7. FEDERAL BUDGET IMPACT:  
a. FFY 2014 Budget Neutral  
b. FFY 2015 Budget Neutral

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Att. 3.1-A, Page 7.5.1, 7.5.2, 7.5.2(a)  
Att. 3.1-B, Page 31, 31.1, 31.1(a)  
Att. 4.19-B, Page 20.1, 20.1(a), 20.1(b), 20.2

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

Same

10. SUBJECT OF AMENDMENT:

This SPA provides for substantive changes to the existing National Medicaid Pooling Initiative (NMPI)  
Supplemental Drug Rebate Agreement

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: Review delegated  
to Commissioner, Department for Medicaid  
Services

12. SIGNATURE OF STATE AGENCY OFFICIAL:

//s//

13. TYPED NAME: Lawrence Kissner

14. TITLE: Commissioner, Department for Medicaid Services

15. DATE SUBMITTED: 11/25/13

16. RETURN TO:

Department for Medicaid Services  
275 East Main Street 6W-A  
Frankfort, Kentucky 40621

**FOR REGIONAL OFFICE USE ONLY**

17. DATE RECEIVED:

12-10-13

18. DATE APPROVED: 01-23-14

**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 as authorized by the state agency email dated 01/09/14.

Block # 8 changed to read: Attachment 3.1-A pages 7.51, 7.52, 7.52(a), 16, Attachment 3.1-B pages 31, 31.1, 31.1(a) 42,  
Attachment 4.19-B pages 20.1, 20.1(a), 20.1(b) and 20.2.

Block # 8 changed to read: Attachment 3.1-A pages 7.51, 7.52, 7.52(a), 16, Attachment 3.1-B pages 31, 31.1, 31.1(a) 42,  
Attachment 4.19-B pages 20.1, 20.1(a), 20.1(b) and 20.2.

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**12. Prescribed Drugs, Dentures, Prosthetic Devices, and Eyeglasses**

If medical necessity is established, limitations in this section do not apply to EPSDT eligible children in accordance with 1905 (r)(5) of the Social Security Act.

**a. Prescribed Drugs**

- (1) Coverage is provided for drugs included in the Medicaid drug lists that are prescribed for outpatient use by a physician, osteopath, dentist, podiatrist, optometrist, physician assistant, or advanced registered nurse practitioner. Drugs added to the Preferred Drug List (PDL) are based on recommendations submitted by the Pharmacy and Therapeutics Advisory Committee to the Commissioner of the Kentucky Department for Medicaid Services for approval. Drugs requiring prior authorization must follow the process listed below. Approval of prior authorization is based on FDA-approved indications or a medically accepted indication documented in official compendia or peer-reviewed medical literature.
- (2) Kentucky will provide reimbursement for covered outpatient drugs when prescribed by an enrolled licensed provider within the scope of their license and practice as allowed by State law and in accordance with Section 1927 of the Social Security Act. This will apply to drugs of any manufacturer that has entered into a rebate agreement with the Centers for Medicare and Medicaid Services (CMS). All drugs covered by the National Drug Rebate Agreements remain available to Medicaid beneficiaries, although some may require prior authorization. The prior authorization process complies with the requirements of Section 1927 of the Social Security Act and provides for a 24-hour turnaround by either telephone or other telecommunications device from receipt of request and provides for a 72- hour supply of drugs in emergency circumstances. The preferred drug list meets the formulary requirements that are specified in Section 1927(d)(4) of the Social Security Act.
- (3) The drugs or classes of drugs listed in 42 USC 1396r-8(d)(2) are excluded from coverage unless specifically placed, either individually or by drug class, on the Medicaid drug lists or prior authorized based on FDA-approved indications or a medically accepted indication documented in official compendia or peer-reviewed medical literature. The following drugs are excluded from coverage through the Outpatient Pharmacy Program:
  - (a) A drug for which the FDA has issued a “less than effective (LTE)” rating or a drug “identical, related, or similar (IRS)” to an LTE drug;
  - (b) A drug that has reached the termination date established by the drug manufacturer;
  - (c) A drug for which the drug manufacturer has not entered into or has not complied with a rebate agreement in accordance with 42 USC 1396r-8(a) unless there has been a review and determination by the department that it shall be in the best interest of Medicaid recipients for the department to make payment for the non-rebated drug. Note: Because federal financial participation is not generally available for a non-rebated drug, state funds will be used to cover such drugs if necessary to protect the health of a Medicaid recipient and no other appropriate options exist;

- (d) A drug provided to a recipient in an institution in which drugs are considered a part of the reasonable allowable costs under the Kentucky Medicaid Program;
  - (e) A drug or its medical use in one (1) of the following categories unless the drug or its medical use is designated as covered in the drug list:
    - 1. A drug if used for anorexia, weight loss, or weight gain;
    - 2. A drug if used to promote fertility;
    - 3. A drug if used for cosmetic purposes or hair growth;
    - 4. A drug if used for the symptomatic relief of cough and colds;
    - 5. Vitamin or mineral products other than prenatal vitamins and fluoride preparations;
    - 6. An over-the-counter drug provided to a Medicaid nursing facility service recipient if included in the nursing facility's standard price;
    - 7. A drug 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; or
    - 8. A drug utilized for erectile dysfunction therapy unless the drug is used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the United States Food and Drug Administration;
  - (f) A drug dispensed as part of, or incident to and in the same setting as, an inpatient hospital service, an outpatient hospital service, or an ambulatory surgical center service. However, a legend drug may be provided through prior authorization to a recipient admitted to an inpatient facility that does not bill patients, Medicaid, or other third-party payers for health care services.
  - (g) A drug for which the department requires prior authorization if prior authorization has not been approved; and
- (4) Except for emergencies, a recipient "locked-in" to one pharmacy due to over-utilization may receive prescriptions:
- (a) Only from his/her designated lock-in pharmacy and prescribed by his/her lock-in provider; or
  - (b) For specified controlled substances prescribed by his/her designated controlled substance lock-in prescriber.
- (5) If authorized by the prescriber, a prescription for a controlled substance in Schedule III-V may be refilled up to five times within a six month period from the date the prescription was written or ordered; a non-controlled substance may be refilled up to 11 times within a 12 month period from the date the prescription was written or ordered. In addition, a prescription fill for a maintenance drug may be dispensed in a 92-day supply if a recipient has demonstrated stability on the maintenance drug. However, a 92-day supply of a maintenance drug shall not be dispensed if a prescribing provider specifies that the quantity should be less. Also, individuals receiving supports for community living services, long term care, and personal care shall not be subject to the 92-day supply requirement.

- (6) A refill of a prescription shall not be covered unless at least 90 percent of the prescription time period has elapsed. However, a refill may be covered before 90 percent of the prescription time period has elapsed if the prescribing provider or dispensing pharmacy submits a prior authorization request by phone, fax, or web submission. Medicaid recipients residing in a long-term care facility or personal care home will be exempt from the 90 percent requirement and remain at the current 80 percent.

- (7) Supplemental Rebate Program:

The state is in compliance with Section 1927 of the Social Security Act. The state has the following policies for the Supplemental Rebate Program for the Medicaid population:

- (a) CMS has authorized the Commonwealth of Kentucky to enter into the Michigan multi-state pooling agreement (MMSPA) also referred to as the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on January 6, 2005 have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA (submitted to CMS on December 10, 2013) has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.
- (b) CMS has authorized Kentucky's collection of supplemental rebates through the NMPI.
- (c) 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 drug rebate agreement.
- (d) All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provision of the national drug rebate agreement.
- (e) Any contracts not authorized by CMS will be submitted for CMS approval in the future.
- (f) As specified in Section 1927(b)(3)(D) of the Act, notwithstanding any other provisions of law, rebate information disclosed by a manufacturer shall not be disclosed by the state for purposes other than rebate invoicing and verification.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State Agency: Kentucky

MEDICAID PROGRAM: REQUIREMENTS RELATING TO PAYMENT FOR COVERED  
OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY

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Citation(s)	Provision(s)
1927(d)(2) and 1935(d)(2)	<input type="checkbox"/> (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 (see specific drug categories below)  (The Medicaid agency lists specific category of drugs below)  Kentucky Medicaid will cover all nonprescription drug categories for full benefit dual eligible beneficiaries, which is consistent with Kentucky's policy of covering all nonprescription drug categories for non-dual recipients. Herbal products are not covered.
	<input type="checkbox"/> No excluded drugs are covered.

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