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State/Territory Name: Kentucky

State Plan Amendment (SPA) #:17-0001

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

May 9, 2017

Stephen P. Miller, Acting Commissioner
Department for Medicaid Services
275 East Main Street, 6WA
Frankfort, KY 40621-0001

Re: Kentucky State Plan Amendment 17-0001

Dear Mr. Miller:

This is to affirm approval of the above referenced State Plan Amendment which was submitted to the Regional Office on March 27, 2017. The State's requested effective date of April 1, 2017 has been accepted.

Enclosed for your records are:

1. a copy of the approval letter dated May 5, 2017 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 Melanie Benning, State Coordinator for Kentucky, at 404-562-7417.

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



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

May 5, 2017

Stephen P. Miller
Commissioner
Department for Medicaid Services
275 East Main Street 6W-A
Frankfort, KY 40621

Dear Mr. Miller:

We have reviewed the Kentucky State Plan Amendment (SPA) TN# 17-0001 received in the Atlanta Regional Office on March 27, 2017, and we are pleased to inform you that it is approved, effective April 1, 2017. Under this SPA, the state of Kentucky specifies how it will revise its pharmacy reimbursement methodology to comply with the key provisions of the Covered Outpatient Drug Final Rule (81 FR 5170) that was published in the Federal Register on February 1, 2016. The rule requires states to pay pharmacies based on the drug ingredient cost, defined as the actual acquisition cost, plus a professional dispensing fee. Kentucky has determined that the weighted average cost of dispensing prescriptions to its Medicaid beneficiaries is \$10.64.

In addition, this SPA proposes to update the state Medicaid program's drugs on which it may exclude from coverage or otherwise restrict in order to comply with the requirements of the 21st Century Cures Act.

The Atlanta Regional Office will forward to you a copy of the CMS-179 form, as well as the pages approved for incorporation into the Kentucky Medicaid state plan. If you have any questions regarding this amendment, please contact Renee Hilliard at (410) 786-2991.

Sincerely,

/s/

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

cc: Jackie Glaze, ARA, Atlanta Regional Office

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL		1. TRANSMITTAL NUMBER: 17-001	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 April 1, 2017	
5. TYPE OF PLAN MATERIAL (<i>Check One</i>):			
<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 (<i>Separate Transmittal for each amendment</i>)			
6. FEDERAL STATUTE/REGULATION CITATION:		7. FEDERAL BUDGET IMPACT: a. FFY 2017 Budget Neutral b. FFY 2018 Budget Neutral	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Att. 3.1-A, Page 15 & 16 Att. 3.1-B, Page 41 & 42 Att. 4.19-B, Page 21.1 – 21.2 Att. 4.19-B, Page 20.4 Att. 4.19-B, Page 20.24		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>): Same	
10. SUBJECT OF AMENDMENT: The purpose of this SPA is to revise our outpatient pharmacy program to comply with the new reimbursement requirements in CMS' Covered Outpatient Drug final rule with comment CMS 2345-FC.			
11. GOVERNOR'S REVIEW (<i>Check One</i>): <input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL <div style="float: right; text-align: right;"> <input checked="" type="checkbox"/> OTHER, AS SPECIFIED: Review delegated to Commissioner, Department for Medicaid Services </div>			
12. SIGNATURE OF STATE AGENCY OFFICIAL: //s//		16. RETURN TO: Department for Medicaid Services 275 East Main Street 6W-A Frankfort, Kentucky 40621	
13. TYPED NAME: Stephen P. Miller			
14. TITLE: Commissioner, Department for Medicaid Services			
15. DATE SUBMITTED: 3/17/17			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED: 03/27/17		18. DATE APPROVED: 05/05/17	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: 04/01/17		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 block # 8, 9, and 10. Block # 8 changes to read: Attachment 3.1-A pages 15, 16; attachment 3.1-B page 41 and 42; 4.19-B pages 20.24, 20.1, 20.1a, 20.1(b), 20.2 and 20.4. Block # 9 changes to read: Attachment 3.1-A pages 15, 16; attachment 3.1-B page 41 and 42; 4.19-B pages 20.24, 20.1, 20.1a, 20.1(b), 20.2 and 20.4. Block 10 change to read: The purpose of this SPA is to revise our outpatient pharmacy program to comply with the new reimbursement requirements in CMS' Covered Outpatient Drug final rule with comment CMS 2345-FC. In addition, this SPA proposes to update the state Medicaid program's drugs on which it may exclude from coverage or otherwise restrict in order to comply with requirements of the 21st Century Cures Act.			

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

Citation (s)	Provision (s)
1927(d)(2) and 1935(d)(2)	<p>1. The Medicaid agency provides coverage for the following 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.</p> <p>— The following excluded drugs are covered:</p> <p><input type="checkbox"/> (a) agents when used for anorexia, weight loss, weight gain (see specific drug categories below)</p> <p><input type="checkbox"/> (b) agents when used to promote fertility (see specific drug categories below)</p> <p><input checked="" type="checkbox"/> (c) agents when used for the symptomatic relief of cough and colds</p> <p><input checked="" type="checkbox"/> (d) prescription vitamins and mineral products, except prenatal vitamins and fluoride</p>

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State Agency: Kentucky

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OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY

Citation(s)	Provision(s)
1927(d)(2) and 1935(d)(2)	<input checked="" type="checkbox"/> (e) nonprescription drugs (see specific drug categories below) Analgesics / Gastrointestinal agents / Vitamins
	<input type="checkbox"/> (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 (see specific drug categories below)
<input type="checkbox"/> No excluded drugs are covered.	

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	<input type="checkbox"/> (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 (see specific drug categories below)
	<input type="checkbox"/> No excluded drugs are covered.

XXV. Advanced Registered Nurse Practitioner Services

(1) Reimbursement

- a. Participating licensed advanced practice registered nurse (APRN) shall be paid only for covered services rendered to eligible recipients and services provided shall be within the scope of practice of a licensed APRN.
- b. Except as specified in subsection c of this section or Section 2 below, reimbursement for a procedure provided by an APRN shall be at the lesser of the following:
 1. The APRN's actual billed charge for the service; or
 2. Seventy-five (75) percent of the amount reimbursable to a Medicaid participating physician for the same service.
- c. An APRN employed by a primary care center, federally qualified health center, hospital, or comprehensive care center shall not be reimbursed directly for services provided in that setting while operating as an employee.

(2) Reimbursement Limitations.

- a. The fee for administration of a vaccine to a Medicaid recipient under the age of twenty-one (21) by an APRN shall be three (3) dollars and thirty (30) cents up to three (3) administrations per APRN, per recipient, per date of service.
- b. The cost of a vaccine provided to a physician or other provider enrolled in the Vaccines for Children (VFC) Program and available free through the Vaccines for Children Program shall not be reimbursed.
- c. For information relating to reimbursement for the cost of drugs administered by a physician or their authorized agent in an office or clinic setting and submitted for reimbursement as a medical benefit, see Attachment 4.19-B, Page 20.1(a).

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- (5) Procedures which are specified by Medicare and published annually in the Federal Register, which are commonly performed in the physician's office, will be reimbursed adjusted rates to take into account the change in usual site of service (facility vs. non-facility based on Medicare Site of Service designation) and are subject to the outpatient upper payment limit.
 - (6) Payments for the injection procedure for chemonucleolysis of intervertebral disk(s), lumbar, shall be paid the lesser of the actual billed charge or \$793.50.
 - (7) Specified family planning procedures in the physician office setting shall be reimbursed at the lesser of the actual billed charges or the Medicaid Physician Fee Schedule plus actual cost of the supply minus ten percent.
 - (8) For information relating to reimbursement for the cost of drugs administered by a physician or their authorized agent in an office or clinic setting and submitted for reimbursement as a medical benefit, see Attachment 4.19-B, Page 20.1(a).
 - (9) When oral surgeons render services which are within the scope of their licensed oral surgery practice, they shall be reimbursed as physicians (i.e., in the manner described above).
 - (10) For practice related services provided by a physician assistant, the participating physician shall be reimbursed at the lesser of the usual and customary charges actual billed charges or 75 percent of the Medicaid Physician Fee Schedule per procedure
 - (11) Any physician participating in the lock-in program will be paid a \$10.00 per month lock-in fee for provision of patient management services for each recipient locked in to that physician.
 - (12) Supplemental payments will be made for services provided by medical school faculty physicians either directly or as supervisors of residents. These payments are in addition to payments otherwise provided under the state plan to physicians that qualify for such payments under the criteria outlined below in Part (a) of this section. The payment methodology for establishing and making the supplemental payments is provided below in Parts (b) and (c) of this section.
 - a. To qualify for a supplemental payment under this section, physicians must meet the following criteria:
 1. Be Kentucky licensed physicians;
 2. Be enrolled as Kentucky Medicaid providers; and
 3. Be Medical School Faculty Physicians as defined in Att 4.19-B, page 20.3, with an agreement to assign their payments to the state-owned academic medical center in accordance with 42 CFR 447.10.

Methods and Standards for Establishing Payment Rates — Other Types of Care

I. Prescribed Drugs

A. Reimbursement.

1. **Lowest of Logic.** Unless otherwise stated, drugs shall be reimbursed at the lowest of:
 - a. The National Average Drug Acquisition Cost (NADAC), plus the professional dispensing fee; or
 - b. The Wholesale Acquisition Cost (WAC) plus zero percent (0%), plus the professional dispensing fee; or
 - c. The Federal Upper Limit (FUL), plus the professional dispensing fee; or
 - d. The Kentucky established Maximum Allowable Cost (MAC), plus the professional dispensing fee; or
 - e. The provider's usual and customary (U&C) charge to the public, as identified by the claim charge.
2. **Retail Community Pharmacy.** Drugs dispensed by a retail community pharmacy will be reimbursed by the lowest of logic in Section A.1.
3. **Specialty Pharmacy.** Drugs not dispensed by a retail community pharmacy but dispensed primarily through the mail (such as specialty drugs) will be reimbursed by the lowest of logic in Section A.1.

- B. **Maximum Allowable Cost (MAC).** MAC is a Kentucky-specific maximum that may be established for any drug for which there are two (2) or more A-rated therapeutically equivalent, multiple-source, non-innovator drugs. The MAC will be determined taking into account each drug's cost, rebate status (non-rebatable, rebatable), marketplace status (obsolete, terminated, regional availability), equivalency rating (A-rated), and relative comparable pricing. Other factors considered are clinical indications of drug substitution, utilization and availability in the marketplace. The Kentucky Medicaid MAC is an acquisition cost based model and includes all types of medications, including specialty and hemophilia products.

Drug pricing resources that may be used to compare actual acquisition costs for multiple-source drugs include:

1. Nationally recognized comprehensive data files maintained by a vendor under contract to the Department, including:
 - a. The National Average Drug Acquisition Cost (NADAC) published by CMS, and
 - b. The Wholesale Acquisition Cost (WAC), manufacturer's price list, and/or other nationally recognized sources
2. The Average Manufacturers Price for 5i Drugs as reported by CMS,
3. Pharmacy providers, and
4. Wholesalers.

- C. **Professional Dispensing Fee.** Effective April 1, 2017, for prescribed drugs, including legend and specific non-legend drugs, prescribed by an authorized provider, Kentucky Medicaid shall reimburse actual acquisition cost for drugs determined by the lowest of logic in Section A.1. and, in all instances, the professional dispensing fee shall be \$10.64 per drug per month.

Methods and Standards for Establishing Payment Rates — Other Types of Care

I. Prescribed Drugs (continued)

4. Institutional Pharmacy. Drugs dispensed by an institutional or long-term care facility pharmacy provider (non-community or non-retail) will be reimbursed by the lowest of logic in Section A.1., plus the professional dispensing fee in Section C.
5. Hemophilia. Clotting factors acquired outside of the 340B Program will be reimbursed by the lowest of logic in Section A.1., which shall include ASP + 6%, plus the professional dispensing fee in Section C.
6. 340B Program.
 - a. 340B covered entities as described in Section 1927(a)(5)(B) of the Social Security Act, including Federally Qualified Health Centers and hemophilia treatment centers, that utilize 340B purchased drugs for Medicaid members will be reimbursed no more than their actual acquisition cost or the amount determined by the lowest of logic in Section A.1., which shall include the 340B Ceiling Price, plus the professional dispensing fee in Section C. Covered entities using drugs purchased under the 340B Program for Medicaid members must bill no more than their actual acquisition cost, plus the professional dispensing fee in Section C.
 - b. 340B covered entities that do not utilize drugs purchased under 340B for Medicaid members will be reimbursed by the lowest of logic in Section A.1., plus the professional dispensing fee in Section C.
 - c. Drugs acquired through the 340B Program and dispensed by 340B contract pharmacies are not covered.
7. Physician Administered Drugs. Drugs administered by a physician or in a hemophilia treatment center submitted under the medical benefit will be reimbursed no more than the lesser of ASP + 6% or the amount determined by the lowest of logic in Section A.1., and no professional dispensing fee shall be paid. Covered entities using drugs purchased under the 340B Program for Medicaid members must bill no more than their actual acquisition cost.
8. Federal Supply Schedule. Facilities purchasing drugs through the Federal Supply Schedule (FSS) will be reimbursed no more than their actual acquisition cost, plus the professional dispensing fee in Section C.
9. Nominal Price. Facilities purchasing drugs at a Nominal Price (outside of 340B or FSS) will be reimbursed no more than their actual acquisition cost, plus the professional dispensing fee in Section C.
10. Investigational Drugs or Investigational Uses of Drugs. Investigational drugs or drugs utilized for non-FDA indications or other investigational treatments are not covered.

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