Table of Contents

State/Territory Name: Kentucky

State Plan Amendment (SPA)#: 20-0007

This file contains the following documents in the order listed

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

July 21, 2020

Lisa D. Lee
The Commissioner
Department for Medicaid Services
275 East Main Street
Frankfort, KY 40601

Dear Ms. Lee:

The CMS Division of Pharmacy team has reviewed Kentucky's State Plan Amendment (SPA) 20-0007 received in the CMS Division of Program Operations on May 13, 2020. This SPA proposes to allow Kentucky to create a single Preferred Drug List (PDL).

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 20-0007 is approved with an effective date of January 1, 2021. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Kentucky's state plan will be forwarded by the CMS Division of Program Operations.

If you have any questions regarding this amendment, please contact Charlotte Amponsah at (410) 786-1092 or charlotte.amponsah@cms.hhs.gov.

Sincerely,

/s/

John Coster, PhD, R.Ph.,
Director
Division of Pharmacy

cc: Sharley Hughes, Federal Program Specialist, Department for Medicaid Services
James G. Scott, Division Director, CMS Division of Program Operations
Keri Toback, CMS Division of Program Operations - East Branch

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB No. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER: 20 — 007

2. STATE: KENTUCKY

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

TO: REGIONAL ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE: January 1, 2021

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 Subpart I

7. FEDERAL BUDGET IMPACT
a. FFY 2021 $ -$8,190,000
b. FFY 2022 $ -$10,920,000

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Att. 3.1-A, Page 7.5.1 and 7.5.2(a)
Att. 3.1-B, Page 31 and 31.1(a)

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*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

10. SUBJECT OF AMENDMENT
The purpose of this SPA is to allow Kentucky to create a single PDL ~~and allow us to enter into value-based contracts with manufacturers on a voluntary basis~~

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

12. SIGNATURE OF STATE AGENCY OFFICIAL

13. TYPED NAME
Lisa D. Lee

14. TITLE
Commissioner

15. DATE SUBMITTED
4/30/2020

16. RETURN TO

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED
5/13/2020

18. DATE APPROVED
7/21/2020

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL
1/1/2021

20. SIGNATURE OF REGIONAL OFFICIAL

21. TYPED NAME
James G. Scott

22. TITLE
Director, Division of Program Operations

23. REMARKS

State authorized pen and ink change to modify language in line 10 to remove "and allow us to enter into value based contracts with manufacturers on a voluntary basis."

Instructions on Back

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. Effective January 1, 2021, the Managed Care Organizations contracted with the Kentucky Department for Medicaid Services (DMS) will follow the preferred drug list established by DMS.

(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 1 927(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;

(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 in July, 2005 supersedes the Kentucky Supplemental Rebate Agreement approved in KY SPA TN 13-026.

(b) Supplemental rebates will be accepted from manufacturers according to the supplemental drug rebate agreement. Supplemental rebates received pursuant to these agreements are only for the Medicaid program and will be collected from manufacturers based on drug utilization for both fee-for-service and managed care plan participants.

(c) CMS has authorized Kentucky's collection of supplemental rebates through the NMPI. The updated agreement applies to drugs dispensed effective January 1, 2021.

(d) 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.

(e) All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provision of the national drug rebate agreement.

(f) Any contracts not authorized by CMS will be submitted for CMS approval in the future.

(g) 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.

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. Effective January 1, 2021, the Managed Care Organizations contracted with the Kentucky Department for Medicaid Services (DMS) will follow the preferred drug list established by DMS.

(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 1 927(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;

(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 in July, 2005 supersedes the Kentucky Supplemental Rebate Agreement approved in KY SPA TN 13-026.

(b) Supplemental rebates will be accepted from manufacturers according to the supplemental drug rebate agreement. Supplemental rebates received pursuant to these agreements are only for the Medicaid program and will be collected from manufacturers based on drug utilization for both fee-for-service and managed care plan participants.

(c) CMS has authorized Kentucky's collection of supplemental rebates through the NMPI. The updated agreement applies to drugs dispensed effective January 1, 2021.

(d) 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.

(e) All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provision of the national drug rebate agreement.

(f) Any contracts not authorized by CMS will be submitted for CMS approval in the future.

(g) 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.