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State/Territory Name: Kentucky

State Plan Amendment (SPA)#:KY-24-0003

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

Medical Benefits Health Programs Group

June 25, 2024

Lisa Lee
Commissioner
Commonwealth of Kentucky
Department for Medicaid Services
275 E. Main St
Frankfort, KY 40601

Dear Lisa Lee:

The CMS Division of Pharmacy team has reviewed Kentucky's State Plan Amendment (SPA) 24-0003 received in the CMS Medicaid Services OneMAC application on March 29, 2024. This SPA proposes to update changes regarding repackaging fees, pricing logic, and the professional dispensing fee for compounded drugs.

In keeping with the requirements of section 1902 (a)(30)(A) of the Social Security Act, we believe the state has demonstrated that their reimbursement is consistent with efficiency, economy, and quality of care, and are sufficient to ensure that care and services are available to Medicaid beneficiaries at least to the extent they are available to the general population in the geographic area. We believe that there is evidence regarding the sufficiency of Kentucky's pharmacy provider network at this time to approve SPA 24-0003. Specifically, Kentucky has reported to CMS that 1,145 of the state's 1,246 licensed in-state retail pharmacies are enrolled in Kentucky's Medicaid program. With a 91 percent participation rate, we can infer that Kentucky's beneficiaries will have access to pharmacy services at least to the extent available to the general population since Medicaid requires that beneficiaries be provided access to all covered outpatient drugs of participating drug manufacturers with a rebate agreement through a broad pharmacy network. In contrast, commercial insurers often have more limited drug formularies and a more limited pharmacy network.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 24-0003 is approved with an effective date of April 1, 2024. Our review was limited to the materials necessary to evaluate the SPA under applicable federal laws and regulations.

We are attaching a copy of the signed CMS-179 form, as well as the page approved for incorporation into Kentucky's state plan. If you have any questions regarding this amendment, please contact Charlotte Hammond at (410) 786-1092 or charlotte.hammond@cms.hhs.gov.

Sincerely,

[redacted]

Mickey D. Morgan
Deputy Director
Division of Pharmacy

cc: Christine Davidson, CMS, Medicaid and CHIP Operations Group
Keri Toback, CMS, Medicaid and CHIP Operations Group
Kelli M. Sheets, Kentucky Medicaid, Federal Program Specialist

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: 24 — 0003

2. STATE: KY

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

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE: 4/1/2024

5. FEDERAL STATUTE/REGULATION CITATION

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2024 $ 0
b. FFY 2025 $ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Att. 4.19-B Pg. 20.1
Att. 4.19-B Pg. 20.1(a)

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
Att. 4.19-B Pg. 20.1
Att. 4.19-B Pg. 20.1(a)

9. SUBJECT OF AMENDMENT
Changes in Pharmacy regarding repacking fees, pricing logic and compound dispense fees.

10. 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:

11. SIGNATURE OF STATE AGENCY OFFICIAL
[redacted]

12. TYPED NAME
Lisa Lee

13. TITLE
Commissioner

14. DATE SUBMITTED
3/29/2024

15. RETURN TO
Lisa Lee
275 E. Main St.
Frankfort, KY 40601

FOR CMS USE ONLY

16. DATE RECEIVED
3/29/2024

17. DATE APPROVED
6/25/2024

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
4/1/2024

19. SIGNATURE
[redacted]

20. TYPED NAME OF APPROVING OFFICIAL
MICKEY MORGAN

21. TITLE OF APPROVING OFFICIAL
DEPUTY DIRECTOR

22. REMARKS

Instructions on Back

INSTRUCTIONS FOR COMPLETING FORM CMS-179

Use Form CMS-179 to transmit State plan material to the Center for Medicaid & CHIP Services for approval. Submit a separate typed transmittal form with each plan/amendment.

Block 1 - Transmittal Number - Enter the State Plan Amendment transmittal number. Assign consecutive numbers on a **calendar year** basis with the first two digits being the two-digit year (e.g., 21-0001, 21-0002, etc.). Because states have different state fiscal years, a calendar year is required for consistency.

Block 2 - State - Enter the two-letter abbreviation code of the State/District/Territory submitting the plan material.

Block 3 - Program Identification - Enter the applicable Title of the Social Security Act (Title XIX Medicaid or Title XXI CHIP).

Block 4 - Proposed Effective Date - Enter the proposed effective date of material. The effective date of a new plan may not be earlier than the first day of the calendar quarter in which an approvable plan is submitted. With respect to expenditures for assistance under such plan, the effective date may not be earlier than the first day on which the plan is in operation on a statewide basis or earlier than the day following publication of notice of changes.

Block 5 - Federal Statute/Regulation Citation - Enter the appropriate statutory/regulatory citation.

Block 6 - Federal Budget Impact - 6(a) - IN WHOLE DOLLARS, NOT IN THOUSANDS, Enter 1st **Federal Fiscal Year** (FFY) impacted by the SPA & estimated Federal share of the cost of the SPA for 1st FFY. The first FFY should be the FFY inclusive of the earliest effective date of any amended payment language; **6 (b)** - Enter 2nd FFY impacted by the SPA & estimated Federal share of the cost for 2nd FFY. In general, the estimates should include any amount not currently approved in the state's plan for assistance.

Block 7 - Page No.(s) of Plan Section or Attachment - Enter the page number(s) of plan material amended and transmitted. If additional space is needed, use bond paper. **New pages** should be included in Block 7, but not in Block 8.

Block 8 - Page No.(s) of the Superseded Plan Section or Attachment (if Applicable) - Enter the page number(s) (including the transmittal number) that is being superseded. If additional space is needed, use bond paper. **Deleted pages** should be included in Block 8, but not in Block 7.

Block 9 - Subject of Amendment - Briefly describe plan material being transmitted.

Block 10 - Governor's Review - Check the appropriate box. See SMM section 13026 A.

Block 11 - Signature of State Agency Official - Authorized State official signs this block.

Block 12 - Typed Name - Type name of State official who signed block 11.

Block 13 - Title - Type title of State official who signed block 11.

Block 14 - Date Submitted - Enter the date that the state transmits plan material to CMCS. Unless the state officially withdraws this SPA and then resubmits it, this date should not be revised. Documentation of version revisions will be maintained in the CMCS administrative record.

Block 15 - Return To - Type the name and address of State official to whom this form should be returned.

Block 16–22 (FOR CMS USE ONLY).

Block 16 - Date Received - Enter the date plan material is received by CMCS. This is the date that the submission is received by CMCS via the subscribed submission process.

Block 17 - Date Approved - Enter the date CMCS approved the plan material.

Block 18 - Effective Date of Approved Material - Enter the date the plan material becomes effective. If more than one effective date, list each provision and its effective date in Block 22 or attach a sheet.

Block 19 - Signature of Approving Official - Approving official signs this block.

Block 20 - Typed Name of Approving Official - Type approving official's name.

Block 21 - Title of Approving Official - Type approving official's title.

Block 22 - Remarks - Use this block to reference and explain agreed to changes and strike-throughs to the original CMS-179 as submitted, a partial approval, more than one effective date, etc. If additional space is needed, use bond paper.

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 Maximum Allowable Cost (MAC) as determined by the state, 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.l.
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.l.

B. **Maximum Allowable Cost (MAC).** The MAC will take into account each drug's cost, rebate status (non-rebatable, rebatable), marketplace status (obsolete, terminated, regional availability), and relative comparable pricing. Other factors considered are clinical indications of drug substitution, utilization, and availability in the marketplace. The Kentucky Medicaid MAC may be applied to covered non-legend over-the-counter drugs and legend drugs including, but not limited to, specialty and biosimilar medications, hemophilia products, etc.

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 Si Drugs as reported by CMS,
3. Pharmacy providers, and
4. Wholesalers.

C. **Dispensing and Repackaging Fees.**

1. **Professional Dispensing Fee.**

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

2. **Unit Dose Repackaging Fee**
   A. For nursing facility residents, meeting Medicaid patient status, an repackaging of two (2) cents per unit dose, but not to exceed $25.00 per claim, shall be paid for repackaging a non-unit dose drug in unit dose form.
   B. Compounded drugs, prescribed by an authorized provider shall reimburse the actual acquisition cost for legend drugs determined by the lowest of logic in Section A.I. and, in all instances, the professional dispensing fee shall be $10.64 every 13 days per compounded drug per individual member per unique pharmacy NPI.

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

I. Prescribed Drugs (continued)

3. 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. I., plus the professional dispensing fee in Section C.
4. Hemophilia. Clotting factors acquired outside of the 340B Program will be reimbursed by the lowest of logic in Section A. I., which shall include ASP+ 6%, plus the professional dispensing fee in Section C.
5. 340B Program.
   a. 340B covered entities as described in Section 1927(a)(5)(8) 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. I., 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. I., plus the professional dispensing fee in Section C.
   c. Drugs acquired through the 340B Program and dispensed by 340B contract pharmacies are not covered.
6. 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 average sales price (ASP) according to the Medicare fee schedule or the amount determined by the lowest of logic in Section A. I., 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.
7. 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.
8. 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.
9. lnvestigational Drugs or Investigational Uses of Drugs. investigational drugs or drugs utilized for non-FDA indications or other investigational treatments are not covered.