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State/Territory Name: Kentucky

State Plan Amendment (SPA) #:KY-23-0008

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form
- 3) Approved SPA Pages

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 25 2023

Lisa Lee Commissioner 275 E. Main St Frankfort, KY 40601

Dear Lisa Lee:

The CMS Division of Pharmacy has reviewed Kentucky's State Plan Amendment (SPA) 23-0008 received in the CMS Medicaid & CHIP Operations Group on March 2, 2023. This SPA proposes to remove the reference to Average Sales Price (ASP) + 6% on the Pharmacy reimbursement State Plan page.

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 23-0008. Specifically, Kentucky has reported to CMS that 1246 of the state's 1061 licensed in-state retail pharmacies are enrolled in Kentucky's Medicaid program. With an 85% 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 23-0008 is approved with an effective date of July 1, 2023.

We are attaching a copy of the signed, revised 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,

Cynthia R. Denemark, R.Ph. Acting Director Division of Pharmacy cc: Kelli M. Sheets, Federal Program Specialist Christine Davidson, Medicaid and CHIP Operations Group Keri Toback, Medicaid and CHIP Operations Group

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	23 - 0008
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	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 July 1, 2023
5. FEDERAL STATUTE/REGULATION CITATION 42 C.F.R. 440.60	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY 2023 \$ 0 b. FFY 2024 \$ 0
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Attachment 4.19-B Page 20.1(a)	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Attachment 4.19-B Page 20.1(a)
9. SUBJECT OF AMENDMENT Changing reimbursement language to read Medicare fee schedule and removing ASP language.	
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	
1	ETURN TO Lisa Lee 275 E. Main St.
12. TYPED NAME Lisa Lee	Frankfort, KY 40601
13. TITLE Commissioner	
14. DATE SUBMITTED 03/02/2023	OF ONLY
16. DATE RECEIVED	
03/02/2023	17. DATE APPROVED 05/25/2023
PLAN APPROVED - ONE COPY ATTACHED	
18. EFFECTIVE DATE OF APPROVED MATERIAL July 1, 2023	19. SIGN
20. TYPED NAME OF APPROVING OFFICIAL CYNTHIA R. DENEMARK	21. TITLE OF APPROVING OFFICIAL ACTING DIRECTOR, DIVISION OF PHARMACY
22. REMARKS	

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.

State: Kentucky
Attachment 4.19-8
Page 20.1(a)

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

I. Prescribed Drugs (continued)

- 4. <u>Institutional Pharmacy.</u> 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.
- 5. <u>Hemophilia.</u> Clotting factors acquired outside of the 340B Program will be reimbursed by the lowest of logic in Section A. I., which shall include rates as noted on the Medicare fee schedule, plus the professional dispensing fee in Section C.

6. <u>340B Program.</u>

- 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.
- 7. Physician Administered Drugs. Drugs administered by a physician or in a hemophilia treatment center submitted under the medical benefit will include rates as noted on 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.
- 8. <u>Federal Supply Schedule</u>. 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. <u>Nominal Price.</u> 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. <u>Investigational Drugs or Investigational Uses of Drugs.</u> investigational drugs or drugs utilized for non-FDA indications or other investigational treatments are not covered.

TN No.: 23-008
Supersedes Approval Date: 05/25/2023 Effective Date: 07/01/2023

TN No.: <u>17-001</u>