Table of Contents

State/Territory Name: Kentucky

State Plan Amendment (SPA)#:KY-25-0005

This file contains the following documents in the order listed:

Approval Letter
CMS 179 Form/Summary Form
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

Medical Benefits Health Programs Group

June18, 2025

Lisa Lee Commissioner 275 East Main St Frankfort, KY 40601

Dear Lisa Lee,

The CMS Division of Pharmacy team has reviewed Kentucky's State Plan Amendment (SPA) 25-0005 received in the CMS Medicaid Services OneMAC application on April 15, 2025. This SPA proposes to allow Kentucky to enter into Value-Based Supplemental Rebate Agreements with drug manufacturers on a voluntary basis.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 25-0005 is approved with an effective date of July 1, 2025. 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 <u>charlotte.hammond@cms.hhs.gov</u>.

Sincerely,

Mickey Morgan Acting Director Division of Pharmacy

cc: Erin Bickers, Federal Program Specialist, Commonwealth of Kentucky Christine Davidson, CMS, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES	
TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	1. TRANSMITTAL NUMBER 2. STATE
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
5. FEDERAL STATUTE/REGULATION CITATION	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY\$
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>)
9. SUBJECT OF AMENDMENT	
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 15. RE Lisa D. Lee	TURN TO
12. TYPED NAME	
13. TITLE	
14. DATE SUBMITTED	
FOR CMS US	EONLY
16. DATE RECEIVED 17 4/15/2025	7. DATE APPROVED 6/18/2025
PLAN APPROVED - ONE	COPY ATTACHED
18. EFFECTIVE DATE OF APPROVED MATERIAL 19 7/1/2025 19). SIGNATURE OF APPROVING OFFICIAL
20. TYPED NAME OF APPROVING OFFICIAL	I. TITLE OF APPROVING OFFICIAL
	ACTING DIRECTOR
MICKEY D. MORGAN	ACTING DIRECTOR

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.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB number for this information collection is 0938-0193. The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, searching existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21224-1850.

- (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 longterm 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 supplemental agreements with drug manufacturers for drugs provided to fee for service and managed care Medicaid beneficiaries, which are covered by a unified preferred drug list (PDL). The Supplemental Rebate Agreement (SRA), titled "Commonwealth of Kentucky Supplemental Rebate Agreement", has been submitted to the Centers for Medicare & Medicaid Services (CMS) on April 25, 2023, and has been authorized to cover supplemental rebates. The Commonwealth of Kentucky will begin using the SRA on January 1, 2024. The pharmaceutical manufacturer agreements and renewals for supplemental rebates may be negotiated by the Sovereign States Drug Consortium (SSDC) multi-state purchasing pool or individually by the Commonwealth of Kentucky.
- (b) CMS has authorized Kentucky's collection of supplemental rebates through the SSDC or through state-negotiated contracts.
- (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.
- (8) (a) The State may enter into value-based contracts with manufacturers on a voluntary basis. These contracts will be executed on the model agreement entitled "Value-Based Supplemental Rebate Agreement" authorized for use beginning July 1st, 2025.

TN No.: <u>2 25-005</u> Supersedes TN No.: <u>23-017</u>

Approval Date: 6/18/2025

Effective Date: 7/1/25

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