

Table of Contents

State/Territory: Louisiana

State Plan Amendment (SPA) #: 24-0019

This file contains the following documents in the order listed:

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

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

October 30, 2024

Kimberly Sullivan
Medicaid Executive Director
Louisiana Department of Health
628 North 4th Street
P.O. Box 91030
Baton Rouge, LA 70821-9030

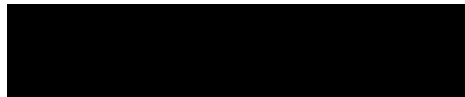
Dear Kimberly Sullivan,

The CMS Division of Pharmacy team has reviewed Louisiana's State Plan Amendment (SPA) 24-0019 received in the CMS Medicaid & CHIP Operations Group on August 21, 2024. This SPA proposes to amend the provision to authorize coverage of drugs authorized for import by the Food and Drug Administration when medically necessary during drug shortages.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 24-0019 is approved with an effective date of October 20, 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 Louisiana's state plan. If you have any questions regarding this amendment, please contact Terry Simananda at (410) 786-8144 or terry.simananda@cms.hhs.gov.

Sincerely,



Cynthia R. Denemark, R.Ph.
Director
Division of Pharmacy

cc: Karen Barnes, Louisiana Department of Health and Human Services
Marjorie Jenkins, Louisiana Department of Health and Human Services
Krystal Ceasor, Louisiana Department of Health and Human Services
Najah Freeman, Louisiana Department of Health and Human Services
Ucheoma Nwagbara, Louisiana Department of Health and Human Services
Tobias Griffin, CMS, Louisiana Medicaid State Lead

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER 24-0019	2. STATE LA
3. PROGRAM IDENTIFICATION: TITLE <u>XIX</u> OF THE SOCIAL SECURITY ACT	
4. PROPOSED EFFECTIVE DATE October 20, 2024	
5. FEDERAL STATUTE/REGULATION CITATION 42 CFR 440.120	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 Attachment 3.1-A, Item 12a, Page 4	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Same (TN 19-0029)

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

5. FEDERAL STATUTE/REGULATION CITATION

42 CFR 440.120

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT


Attachment 3.1-A, Item 12a, Page 4

9. SUBJECT OF AMENDMENT
The purpose of this SPA is to amend the provisions governing the Pharmacy Benefits Management Program in order to align the language relative to shortages of drugs not on the covered drug list, including drugs authorized for import by the Food and Drug Administration (FDA) that may be covered when deemed medically necessary during drug shortages identified by the FDA, with CMS requirements.

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:
The Governor does not review State Plan material.

11. SIGNATURE OF STATE AGENCY OFFICIAL

12. **Michael Harrington, MBA, MA**

13. TITLE
Secretary

14. DATE SUBMITTED
August 21, 2024

15. RETURN TO
**Kimberly Sullivan, J.D.
Medicaid Executive Director
Louisiana Department of Health
628 North 4th Street
P.O. Box 91030
Baton Rouge, LA 70821-9030**

FOR CMS USE ONLY

16. DATE RECEIVED
August 21, 2024

17. DATE APPROVED
October 30, 2024

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
October 20, 2024

19. 

20. TYPED NAME OF APPROVING OFFICIAL
Cynthia R. Denmark, R.Ph.

21. TITLE OF APPROVING OFFICIAL
Director, Division of Pharmacy

22. REMARKS

STATE OF LOUISIANA

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED
LIMITATIONS ON THE AMOUNT, DURATION AND SCOPE OF CERTAIN ITEMS OF
PROVIDED MEDICAL AND REMEDIAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

- d. Manufacturers are allowed to audit utilization data;
 - e. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification; and
 - f. The Department will utilize the same processes to resolve State Supplemental rebate issues as it uses to resolve federal rebate disputes and as outlined in CMS' *Best Practices Guide for Dispute Resolution Under the Medicaid Drug Rebate Program*.
4. The Department is also in compliance with state regulations relative to the confidentiality of supplemental rebate information contained in the records of the Department and its agents.
 5. CMS has authorized the template for the State of Louisiana to enter into a single, state-specific Supplemental Rebate Agreement between the State and a drug manufacturer(s) for both fee-for-service and those paid by contracted managed care organizations (MCOs) in the Medicaid program, submitted to CMS on May 15, 2019, entitled "*State of Louisiana Supplemental Rebate Agreement*" and has been authorized by CMS effective July 1, 2019.
 6. CMS has authorized the state of Louisiana to enter into *The Optimal PDL Solution (TOP\$)*. This Supplemental Drug Rebate Agreement was submitted to CMS on November 5, 2013, and has been authorized by CMS effective October 1, 2013. The TOP\$ supplemental rebate agreements would apply to the drug benefit, both fee-for-service and those paid by contracted managed care organizations (MCOs), under prescribed conditions in Attachment A-2 of the TOP\$ Supplemental Rebate Agreement, effective May 1, 2019.
 7. The Department may enter into an agreement with a pharmaceutical manufacturer for outcomes-based contracts on a voluntary basis. The contracts will be executed on a model agreement entitled "*Value-Based Supplemental Rebate Agreement*" submitted to CMS on December 30, 2019, with an effective date of January 20, 2020.

E. Single State-Managed Preferred Drug List

Effective May 1, 2019, the Department shall implement a single state-managed PDL for all participating MCOs and for fee-for-service.

F. Drug Shortages

Prescribed drugs that are not covered outpatient drugs, including drugs authorized for import by the Food and Drug Administration (FDA), may be covered when deemed medically necessary during drug shortages identified by the FDA, as listed on the state's website.