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State/Territory Name: Louisiana

State Plan Amendment (SPA) #: 19-0029

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form
- 3) Approved 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

Disabled and Elderly Health Programs Group

March 11, 2020

Ms. Erin Campbell, Acting Medicaid Director
State of Louisiana
Department of Health
628 N 4th St
PO Box 91030
Baton Rouge, LA 70821-9030

Dear Ms. Campbell:

We have reviewed Louisiana State Plan Amendment (SPA) 19-0029 received in the Centers for Medicare & Medicaid Services (CMS) Division of Program Operations West Branch on December 30, 2019. This SPA proposes to allow the Louisiana Medicaid Agency to enter into value/outcome(s) based agreements with drug manufacturers for purposes of collecting additional supplemental drug rebates.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 19-0029 is approved with an effective date of January 20, 2020. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Louisiana's state plan will be forwarded by the Division of Program Operations West Branch.

If you have any questions regarding this request, please contact Justin Aplin at (410) 786-6901 or Justin.Aplin@cms.hhs.gov.

Sincerely,

/s/

Cynthia R. Denemark, R.Ph.
Deputy Director
Division of Pharmacy
DEHPG/CMCS/CMS

cc: Rebekah E. Gee, Secretary
Cindy Rives, Undersecretary
James G. Scott, Director
Tobias Griffin

Louisiana Department of Health
Louisiana Department of Health
Division of Program Operations
Division of Program Operations West Branch

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

1. TRANSMITTAL NUMBER
19-0029

2. STATE
Louisiana

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 20, 2020

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 440.120
42 CFR 447 Subpart I**

7. FEDERAL BUDGET IMPACT

- a. FFY **2020** \$ **0**
b. FFY **2021** \$ **0**

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

**Attachment 3.1-A, Item 12a, Pages 1 and 2
Attachment 3.1-A, Item 12a, Page 4**

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

**Same (TN 17-0008)
Same (TN 19-0018)**

10. SUBJECT OF AMENDMENT **The purpose of this SPA is to amend the provisions governing the Pharmacy Benefits Management program in order to allow the State to pursue outcomes-based agreements with manufacturers and to align the provisions with the current Medicaid State Plan.**

11. GOVERNOR'S REVIEW (Check One)

- GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED The Governor does not review State Plan material.
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL

13. TYPED NAME

Cindy Rives, designee for Rebekah E. Gee MD, MPH

14. TITLE

Secretary

15. DATE SUBMITTED

December 30, 2019

16. RETURN TO

**Erin Campbell, Acting Medicaid Director
State of Louisiana
Department of Health
628 North 4th Street
P.O. Box 91030
Baton Rouge, LA 70821-9030**

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED

December 30, 2019

18. DATE APPROVED

March 11, 2020

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL

January 20, 2020

20. SIGNATURE OF REGIONAL OFFICIAL

21. TYPED NAME

James G. Scott

22. TITLE

Director, Division of Program Operations

23. 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:

<u>CITATION</u>	Medical and Remedial	<u>Prescribed drugs, and Prosthetic Devices; and Eyeglasses</u>
42 CFR	Care and Services	<u>Prescribed by a Physician Skilled in Diseases of the Eye or by</u>
440.120	Item 12.a.	<u>an Optometrist</u>

Item 12.a. Prescribed drugs are limited as follows:

Vendor payments are made for prescribed medications and/or supplies. The medications must be prescribed by a practitioner authorized to prescribe under State law. The National Drug Code (NDC) must be shown on each pharmaceutical claim form for reimbursement of prescription drugs subject to rebates from manufacturers as prescribed by mandatory federal law and regulations.

A. Drugs for Full Benefit Dual Eligible

Effective January 1, 2006, Louisiana Medicaid will not reimburse any drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B, which would entitle the dual eligible individual to receive drug benefits under the Medicare Prescription Drug Benefit, Part D. The only drugs covered for the full-benefit dual eligible by Louisiana Medicaid are those subject to restriction under Section 1927(d) (2) of the Social Security Act.

B. Medicaid Coverage of Drugs Restricted Under Section 1927(d) (2) of the Social Security Act

The Medicaid Program will provide coverage for the following drugs which may be excluded, or otherwise restricted, under the provisions of Section 1927(d)(2) of the Social Security Act. The Medicaid agency will not pay when Medicare Part B or Part D plans reimburse for these drugs.

Excluded Drugs:

- Select agents when used for anorexia, weight loss, or weight gain, except
Xenical only
- Select agents when used to promote fertility, except
Vaginal progesterone when used for high-risk pregnancy to prevent premature births
- Select agents when used for symptomatic relief of cough and colds, except
Prescription antihistamine and antihistamine/decongestant combination products

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:

- Select prescription vitamins and mineral products, except

Prenatal vitamins
Fluoride preparations
Vitamin A injection
Vitamin B injection
Vitamin D (prescription only)
Vitamin K (prescription only)
Vitamin B12 injection
Folic Acid (prescription only)
Niacin (prescription only)
Vitamin B6 injection
Vitamin B1 injection
Multivitamin (prescription only)
Magnesium injection
Calcium injection
Urinary PH modifiers (Phosphorous, specifically K Phos Neutral and Phospha Neutral)

- Select nonprescription drugs, except

OTC antihistamines and antihistamine/decongestant combinations
Miralax

- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

Otherwise Restricted Drugs:

- The state will cover agents when used for cosmetic purposes or hair growth only when the state has determined that use to be medically necessary.

- Select drugs for erectile dysfunction, except
When used for the treatment of conditions, or indications approved by the FDA, other than erectile dysfunction.

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.