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State/Territory Name: Louisiana

State Plan Amendment (SPA) #: 13-44 Pharm

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 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



Disabled & Elderly Health Programs Group

March 14, 2014

J. Ruth Kennedy
State Medicaid Director
Louisiana Department of Health and Hospitals
628 N. 4th Street
P.O. Box 91030
Baton Rouge, Louisiana 70821

Attention: Darlene York

Dear Ms. Kennedy:

We have reviewed Louisiana State Plan Amendment (SPA) 13-44, Prescribed Drugs – Supplemental Rebate Agreement, received in the Dallas Regional Office on December 27, 2013. Louisiana proposes to continue participation in *The Optimal PDL Solution (TOP\$sm)*, a multi-state pooling supplemental rebate agreement. The contract has been revised adding definitions and structural changes that provide the option of including Medicaid Managed Care Organization (MCO) utilization for accrual of supplemental rebates. Inclusion of the MCO population under the contract is optional and at the sole discretion of the state.

If revisions are subsequently made to include MCO utilization for supplemental rebate collection or any other changes to the supplemental drug rebate agreement, attachments or schedules, all such documents should be submitted to CMS for review and approval. A separate SPA will be required if the state intends to exercise the option of including MCO utilization for supplemental rebates.

Based on the information provided, we are pleased to inform you that Louisiana SPA 13-44 is approved with an effective date of October 1, 2013. The approval extends only to the authority of the state to enter into a supplemental rebate agreement under section 1927 of the Social Security Act. A copy of the CMS-179 form, as well as the pages approved for incorporation into the Louisiana state plan, will be forwarded by the Dallas Regional Office. If you have any questions regarding this amendment, please contact Bernadette Leeds at (410) 786-9463.

Sincerely,

/s/

Kim Howell
Acting Director
Division of Pharmacy

cc: Bill Brooks, ARA, Dallas Regional Office
Ford Blunt, Dallas Regional Office
Darlene Adams, Louisiana Department of Health and Hospitals

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: HEALTH CARE FINANCING ADMINISTRATION	1. TRANSMITTAL NUMBER: 13-44	2. STATE Louisiana
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE October 1, 2013	

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: Section 1927 of the Social Security Act 42 CFR 440.120 Subpart A	7. FEDERAL BUDGET IMPACT: a. FFY <u>2014</u> (\$24,182.18) 0 b. FFY <u>2015</u> (\$3,626.40) 0
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8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A, Item 12a, Page 5 Attachment 3.1-A, Item 12.a, Page 5a	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Supersedes (TN 04-26) Attachment 3.1-A, Item 12a, Page 5 None (new page)
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10. SUBJECT OF AMENDMENT: **This State Plan Amendment provides for substantive changes to the existing TOPSSM The Optimal PDL \$solution ("TOPS") State Supplemental Rebate Agreement ("SRA"), which includes revised definitions, and structural changes to the SRA.**

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:	16. RETURN TO: J. Ruth Kennedy, Medicaid Director State of Louisiana Department of Health and Hospitals 628 N. 4th Street PO Box 91030 Baton Rouge, LA 70821-9030
13. TYPED NAME: Kathy H. Kliebert	
14. TITLE: Secretary	
15. DATE SUBMITTED: December 30, 2013	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 27 December, 2013	18. DATE APPROVED: 14 March, 2014
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PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 1 October, 2013	20. SIGNATURE: [REDACTED] OFFICIAL:
21. TYPED NAME: BILL BROOKS	22. TITLE: Associate regional Administrator Division of Medicaid & Children's Health

23. REMARKS: **The State requests pen and ink changes to Blocks 6, 8 and 9.**
Per e-mail from state dated 3-13-14.

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

3. Rebate agreements between the state and a drug manufacturer that are separate from the drug rebate agreements of Section 1927 are approved by the Centers for Medicare and Medicaid Services. The state reports rebates from separate agreements to the Secretary for Health and Human Services. The state will remit the federal portion of any state supplemental rebates collected.
 4. Manufacturers are allowed to audit utilization data.
 5. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.
 6. 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*.
- D. The Department is also in compliance with R.S. 44:4 as amended by Act 124 of The First Extraordinary Session of the 2002 Legislature relative to the confidentiality of supplemental rebate information contained in the records of the Department and its agents.
- E. A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on April 8, 2002 and entitled "Supplemental Rebate Agreement" was previously authorized by CMS on April 25, 2002.
- F. 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.

State: Louisiana
Date Received: 12-23-13
Date Approved: 3-14-14
Date Effective: 10-1-13
Transmittal Number: LA 13-44