

NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Pharmacy Benefits Management Program
Managed Care Supplemental Rebates
(LAC 50:XXIX.1103)

The Department of Health, Bureau of Health Services Financing proposes to adopt LAC 50:XXIX.1103 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health, Bureau of Health Services Financing promulgated a Rule which amended the provisions governing the Pharmacy Benefits Management Program in order to establish provisions for the Medicaid Program's participation in The Optimal PDL Solution (TOP\$) State Supplemental Rebate Agreement Program and assure compliance with the technical requirements of R.S. 49:953 (*Louisiana Register*, Volume 43, Number 5).

The department has now determined that it is necessary to amend the provisions governing the TOP\$ State Supplemental Rebate Agreement Program in order to include pharmacy utilization of managed care organizations (MCOs) that participate in the Healthy Louisiana (formerly Bayou Health) Program and implement a single state managed preferred drug list

for selected therapeutic classes to maximize supplemental rebates on MCO utilization.

Title 50

**PUBLIC HEALTH-MEDICAL ASSISTANCE
Part XXIX. Pharmacy**

Chapter 11. State Supplemental Rebate Agreement Program

§1103. Managed Care Organization Utilization

A. Effective for dates on or after October 1, 2017, the TOP\$ State Supplemental Rebate Agreement Program shall include pharmacy utilization of managed care organizations (MCOs) that participate in the Healthy Louisiana Program for state supplemental drug rebates on selected therapeutic classes.

1. The Healthy Louisiana Program's contracts with the participating MCOs shall:

a. allow inclusion of the pharmacy utilization data for supplemental rebate purposes; and

b. mandate that each participating MCO shall align their respective formulary(ies) and/or preferred drug list (PDL) on selected therapeutic classes, as applicable, to the fee-for-service (FFS) preferred drug list and adopt FFS prior authorization criteria for the non-preferred agents.

B. The Department of Health shall implement a single state managed PDL for selected therapeutic classes for all participating MCOs in order to maximize the supplemental and federal rebates on MCO utilization.

C. Supplemental rebates on MCO utilization shall be excluded from best price or average manufacturer price (AMP) calculations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability and autonomy as described in R.S. 49:972.

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the

provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, no direct or indirect cost to the provider to provide the same level of service, and will have no impact on the provider's ability to provide the same level of service as described in HCR 170.

Interested persons may submit written comments to Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030 or by email to MedicaidPolicy@la.gov. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. A public hearing on this proposed Rule is scheduled for Thursday, July 27, 2017 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Rebekah E Gee MD, MPH

Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person

Preparing

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Rule Title: Pharmacy Benefits
Management Program
Managed Care
Supplemental Rebates

Date Rule Takes Effect: October 1, 2017

SUMMARY

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. The following summary statements, based on the attached worksheets, will be published in the Louisiana Register with the proposed agency rule.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (SUMMARY)

It is anticipated that implementation of this proposed rule will result in estimated state general fund costs of \$216 for FY 16-17 and programmatic savings of \$4,997,340 for FY 17-18 and \$21,158,895 for FY 18-19. The estimated savings includes increased revenue of \$580,139 for FY 17-18 and \$3,327,725 for FY 18-19 from the Medicaid Assistance Trust Fund premium taxes. It is anticipated that \$432 (\$216 SGF and \$216 FED) will be expended in FY 16-17 for the state's administrative expense for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 63.34 percent in FY 17-18 and 64.23 percent in FY 18-19 for the projected non-expansion population, and a blended FMAP rate of 94.5 percent in FY 17-18 and 93.5 percent in FY 18-19 for the projected expansion population.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed rule will increase federal revenue collections by \$216 for FY 16-17 and reduce federal revenue collections by approximately \$14,139,268 for FY 17-18 and \$53,291,638 for FY 18-19. It is anticipated that \$216 will be expended in FY 16-17 for the federal administrative expenses for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 63.34 percent in FY 17-18 and FY 18-19 and a blended FMAP rate of 94.5 percent in FY 17-18 and 93.5 percent in FY 18-19 for the projected expansion population.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

This proposed rule amends the provisions governing the TOP\$ State Supplemental Rebate Agreement Program in order to include pharmacy utilization of managed care organizations (MCOs) that participate in the Healthy Louisiana (formerly Bayou Health) Program, and to implement a single state managed preferred drug list for selected therapeutic classes to maximize supplemental rebates on MCO utilization. It is anticipated that implementation of this proposed rule will reduce programmatic expenditures in the pharmacy benefits management program by approximately \$18,556,470 for FY 17-18 and \$71,122,808 for FY 18-19.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.



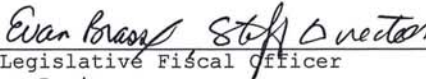
Signature of Agency Head
or Designee

Jen Steele, Medicaid Director

Typed name and Title of
Agency Head or Designee



LDH/BHSF Budget Head



Legislative Fiscal Officer
or Designee

6/8/17

Date of Signature

06/08/17

Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberations on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

This proposed rule amends the provisions governing the TOP\$ State Supplemental Rebate Agreement Program in order to include pharmacy utilization of managed care organizations (MCOs) that participate in the Healthy Louisiana (formerly Bayou Health) Program, and to implement a single state managed preferred drug list for selected therapeutic classes to maximize supplemental rebates on MCO utilization.

- B. Summarize the circumstances that require this action. If the action is required by federal regulations, attach a copy of the applicable regulation.

The Department of Health, Bureau of Health Services Financing promulgated a Rule which amended the provisions governing the Pharmacy Benefits Management Program in order to establish provisions for the Medicaid Program's participation in The Optimal PDL Solution (TOP\$) State Supplemental Rebate Agreement Program and assure compliance with the technical requirements of R.S. 49:953 (Louisiana Register, Volume 43, Number 5).

The department has now determined that it is necessary to amend the provisions governing the TOP\$ State Supplemental Rebate Agreement Program in order to include pharmacy utilization of managed care organizations (MCOs) that participate in the Healthy Louisiana (formerly Bayou Health) Program and implement a single state managed preferred drug list for selected therapeutic classes to maximize supplemental rebates on MCO utilization.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session.

- (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

This proposed rule will result in an increase in costs of \$432 for FY 16-17 and a reduction in programmatic expenditures by approximately \$18,556,470 for FY 17-18 and \$71,122,808 for FY 18-19. In FY 16-17, \$432 is included for the state's administrative expense for promulgation of this proposed rule and the final rule.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

- (a) If yes, attach documentation.
(b) If no, provide justification as to why this rule change should be published at this time.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COST OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase or (decrease) in cost to implement the proposed action?

COST	FY 16-17	FY 17-18	FY 18-19
PERSONAL SERVICES			
OPERATING EXPENSES	\$432	\$0	\$0
PROFESSIONAL SERVICES			
OTHER CHARGES	\$0	(\$18,556,470)	(\$71,122,808)
REPAIR & CONSTR.			
POSITIONS (#)			
TOTAL	\$432	(\$18,556,470)	(\$71,122,808)

2. Provide a narrative explanation of the costs or savings shown in "A.1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

The expenses reflected above are the estimated increases in expenditures in the Medicaid program for FY 16-17 and decreases in FY 17-18 and FY 18-19. In FY 16-17, \$432 is included for the state's administrative expense for promulgation of this proposed rule and the final rule.

3. Sources of funding for implementing the proposed rule or rule change.

Source	FY 16-17	FY 17-18	FY 18-19
STATE GENERAL FUND	\$216	(\$4,997,340)	(\$21,158,895)
SELF-GENERATED			
FEDERAL FUND	\$216	(\$14,139,269)	(\$53,291,638)
OTHER (Specify) <i>Medicaid Assistance Trust Fund Premium Taxes used as an offset to the General Fund</i>		\$580,139	\$3,327,725
Total	\$432	(\$18,556,470)	(\$71,122,808)

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

Yes, sufficient funds are available to implement this rule.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THIS PROPOSED ACTION.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustment in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

This proposed rule has no known impact on local governmental units.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

2. Indicate the sources of funding of the local governmental unit that will be affected by these costs or savings.

There is no known impact on the sources of local governmental unit funding.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

- A. What increase or (decrease) in revenues can be expected from the proposed action?

REVENUE INCREASE/DECREASE	FY 16-17	FY 17-18	FY 18-19
STATE GENERAL FUND			
AGENCY SELF-GENERATED			
RESTRICTED FUNDS*			
FEDERAL FUNDS	\$216	(\$14,139,269)	(\$53,291,638)
LOCAL FUNDS			
Total	\$216	(\$14,139,269)	(\$53,291,638)

**Specify the particular fund being impacted*

- B. Provide a narrative explanation of each increase or decrease in revenue shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

The amounts reflected above are the estimated increases in the federal share of programmatic expenditures for the Medicaid program in FY 16-17 and decreases in FY 17-18 and FY 18-19. In FY 16-17, \$216 is included for the federal expense for promulgation of this proposed rule and the final rule.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

- A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effects on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.)

This proposed rule amends the provisions governing the TOP\$ State Supplemental Rebate Agreement Program in order to include pharmacy utilization of managed care organizations (MCOs) that participate in the Healthy Louisiana (formerly Bayou Health) Program, and to implement a single state managed preferred drug list for selected therapeutic classes to maximize supplemental rebates on MCO utilization.

- B. Also, provide an estimate of any revenue impact resulting from this rule or rule change to these groups.

It is anticipated that implementation of this proposed rule will reduce programmatic expenditures in the pharmacy benefits management program by approximately \$18,556,470 for FY 17-18 and \$71,122,808 for FY 18-19.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

This rule has no known effect on competition and employment.