

## **NOTICE OF INTENT**

### **Department of Health Bureau of Health Services Financing**

#### **Pharmacy Benefits Management Program State Supplemental Rebate Agreement Program (LAC 50:XXIX.Chapter 11)**

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.Chapter 11 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 established provisions in the Pharmacy Benefits Management Program governing the Medicaid Program's participation in The Optimal PDL Solution (TOP\$) State Supplemental Rebate Agreement Program (Louisiana Register, Volume 43, Number 5). The department now proposes to amend the provisions governing the State Supplemental Rebate Agreement Program in order to remove the requirement for participation in a specific supplemental rebate agreement.

### **Title 50**

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

#### **Chapter 11. State Supplemental Rebate Agreement Program**

#### **§1101. General Provisions**

A. The Centers for Medicare and Medicaid Services approved LDH to enter into state supplemental rebate agreements with pharmaceutical manufacturer(s). LDH may enter into an agreement with a pharmaceutical manufacturer to obtain a rebate(s) in addition to federal rebates pursuant to 42 U.S.C. 1396r. Participation by a pharmaceutical manufacturer in a state supplemental rebate agreement with the department is voluntary.

B. Repealed.

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 43:966 (May 2017), amended LR 45:

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. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at close of business, 4:30 p.m., on May 30, 2019.

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton

Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on May 10, 2019. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on May 30, 2019 in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Stanley Bordelon at (225) 219-3454 after May 10, 2019. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Rebekah E. Gee MD, MPH

Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

Person

Preparing

Statement: Veronica Dent

Phone: 342-3238

Dept.: Health

Office: Bureau of Health Services  
Financing

Return P.O. Box 91030

Address: Baton Rouge, LA

Rule Title: Pharmacy Benefits Management  
Program  
State Supplemental Rebate  
Agreement Program

Date Rule Takes Effect: July 20, 2019

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 have no programmatic fiscal impact to the state other than the cost of promulgation for FY 18-19. It is anticipated that \$432 (\$216 SGF and \$216 FED) will be expended in FY 18-19 for the state's administrative expense for promulgation of this proposed rule and the final rule.*

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

*It is anticipated that the implementation of this proposed rule will have no effect on revenue collections other than the federal share of the promulgation costs for FY 18-19. It is anticipated that \$216 will be collected in FY 18-19 for the federal share of the expense for promulgation of this proposed rule and the final rule. This technical change allows the Department the flexibility within the Medicaid pharmacy program to negotiate various rebate agreements that may impact rebate revenues.*

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

*This proposed rule amends the provisions governing the Pharmacy Benefits Management Program in order to remove the requirement for participation in The Optimal PDL Solution (TOP\$) State Supplemental Rebate Agreement Program and allow for non-specific state supplemental rebate agreements. It is anticipated that implementation of this proposed rule will not result in programmatic costs or benefits to pharmacy providers in FY 18-19, FY 19-20 and FY 20-21.*

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

4 / 10 / 19  
\_\_\_\_\_  
Date of Signature

04/10/19  
\_\_\_\_\_  
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 Pharmacy Benefits Management Program in order to remove the requirement for participation in The Optimal PDL Solution (TOPS) State Supplemental Agreement Program and allow for non-specific state supplemental rebate agreements.*

- 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 established provisions in the Pharmacy Benefits Management Program governing the Medicaid Program's participation in The Optimal PDL Solution (TOPS) State Supplemental Rebate Agreement Program (Louisiana Register, Volume 43, Number 5). The department now proposes to amend the provisions governing the State Supplemental Rebate Agreement Program in order to remove the requirement for participation in a specific supplemental rebate agreement.*

- 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.

*No. It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 18-19. In FY 18-19, \$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 18-19	FY 19-20	FY 20-21
PERSONAL SERVICES			
OPERATING EXPENSES	\$432	\$0	\$0
PROFESSIONAL SERVICES			
OTHER CHARGES			
REPAIR & CONSTR.			
POSITIONS (#)			
<b>TOTAL</b>	<b>\$432</b>	<b>\$0</b>	<b>\$0</b>

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.

*In FY 18-19, \$432 will be spent 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 18-19	FY 19-20	FY 20-21
STATE GENERAL FUND	\$216	\$0	\$0
SELF-GENERATED			
FEDERAL FUND	\$216	\$0	\$0
OTHER (Specify)			
<b>Total</b>	<b>\$432</b>	<b>\$0</b>	<b>\$0</b>

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 18-19	FY 19-20	FY 20-21
STATE GENERAL FUND			
AGENCY SELF-GENERATED			
RESTRICTED FUNDS*			
FEDERAL FUNDS	\$216	\$0	\$0
LOCAL FUNDS			
<b>Total</b>	<b>\$216</b>	<b>\$0</b>	<b>\$0</b>

**\*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.

*In FY 18-19, \$216 will be collected for the federal share of the administrative 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 Pharmacy Benefits Management Program in order to remove the requirement for participation in The Optimal PDL Solution (TOP\$) State Supplemental Rebate Agreement Program and allow for non-specific state supplemental rebate agreements.*

- 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 not result in programmatic costs or benefits to pharmacy providers in FY 18-19, FY 19-20 and FY 20-21.*

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.*