

NOTICE OF INTENT

Department of Health Bureau of Health Services Financing

Pharmacy Benefits Management Program Physician-Administered Drugs Reimbursement Methodology (LAC 50:XXIX.949)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.949 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 U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) mandated that the Department of Health, Bureau of Health Services Financing revise the reimbursement methodology for physician-administered drugs in a physician office setting in order to bring the rates current and to incorporate a mechanism for periodic updates to the rates. In compliance with CMS requirements, the department proposes to amend the provisions governing the Pharmacy Benefits Management Program to revise the reimbursement methodology for physician-administered drugs.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE Part XXIX. Pharmacy

Chapter 9. Methods of Payment

Subchapter D. Maximum Allowable Costs

§949. Fee for Service Cost Limits

A. - H. ...

I. Physician-Administered Drugs. Medicaid covered physician-administered drugs shall be reimbursed according to the Louisiana professional services fee schedule. Reimbursement shall be determined utilizing the following methodology, and periodic updates to the rates shall be made in accordance with the approved Louisiana Medicaid State Plan provisions governing physician-administered drugs in a physician office setting.

1. Reimbursement for Medicaid covered physician-administered drugs in a physician office setting shall be established at the current Louisiana Medicare rate, which is average sales price (ASP) plus 6 percent, for drugs appearing on the Medicare file.

2. Reimbursement rates for physician-administered drugs in a physician office setting that do not appear on the Medicare file shall be determined utilizing the following alternative methods:

a. the wholesale acquisition cost (WAC) of the drug, if available;

b. If the drug has no WAC available, one of the following methods shall be used:

i. the provider's actual cost of the drug as documented by invoice or other acceptable documentation as deemed appropriate by the department;

ii. Medicaid rate of other states;

iii. commercial payer rate; or

iv. medical consultant recommendation.

J. - K. ...

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 and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1065 (June 2006), amended LR 34:88 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1561 (July 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1185 (June 2017), LR 43:1554 (August 2017), LR 44:

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, but may impact payments to providers due to the adjustment to current pricing for some physician-administered drugs. It is anticipated that this proposed Rule 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, April 26, 2018 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
Physician-Administered Drugs
Reimbursement Methodology

Date Rule Takes Effect: June 20, 2018

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 no programmatic fiscal impact to the state in FY 17-18 other than the cost of promulgation. This proposed rule is anticipated to result in estimated state general fund programmatic costs of approximately \$62,000 for FY 18-19 and \$95,827 for FY 19-20. It is anticipated that \$540 (\$270 SGF and \$270 FED) will be expended in FY 17-18 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 implementation of this proposed rule will not affect revenue collections in FY 17-18 other than the federal share of the promulgation costs. This proposed rule is anticipated to result in increased federal revenue collections of approximately \$204,154 for FY 18-19 and \$296,400 for FY 19-20. It is anticipated that \$270 will be collected in FY 17-18 for the federal share of the administrative expense for promulgation of this proposed rule and the final rule.

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

In compliance with U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services mandates, this proposed rule amends the provisions governing the Pharmacy Benefits Management Program to revise the reimbursement methodology for physician-administered drugs in a physician office setting in order to bring the rates into alignment with the 2018 Louisiana Medicare rate, and to incorporate a mechanism for periodic updates to the rates. This proposed Rule will impact payments to providers due to the adjustment to current pricing for some physician-administered drugs. It is anticipated that implementation of this proposed rule will increase programmatic expenditures in the Pharmacy Benefits Management Program by approximately \$266,154 for FY 18-19 and \$392,227 for FY 19-20.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.



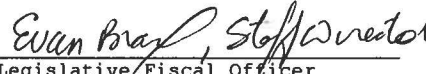
Signature of Agency Head
or Designee

Jen Steele, Medicaid Director

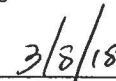
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Agency Head or Designee



LDH/BHSF Budget Head



Legislative/Fiscal Officer
or Designee



Date of Signature



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).

In compliance with U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services mandates, this proposed rule amends the provisions governing the Pharmacy Benefits Management Program to revise the reimbursement methodology for physician-administered drugs in a physician office setting in order to bring the rates current, and to incorporate a mechanism for periodic updates to the rates.

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

The U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) mandated that the Department of Health, Bureau of Health Services Financing revise the reimbursement methodology for physician-administered drugs in a physician office setting in order to bring the rates current and to incorporate a mechanism for periodic updates to the rates. In compliance with CMS requirements, the department proposes to amend the provisions governing the Pharmacy Benefits Management Program to revise the reimbursement methodology for physician-administered drugs.

- 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.

Yes. This proposed rule will result in an increase in programmatic expenditures by approximately \$540 for FY 17-18, \$266,154 for FY 18-19 and \$392,227 for FY 19-20. In FY 17-18, \$540 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.

Act 15 of the 2017 Regular Session of the Louisiana Legislature allocated funds to the Medical Vendor Program for payments to providers and thereby authorizes the expenditure of these funds. The rule change should be published at this time to avoid sanctions from CMS for non-compliance with federal regulatory requirements relative to physician-administered drugs in physician office settings.

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 17-18	FY 18-19	FY 19-20
PERSONAL SERVICES			
OPERATING EXPENSES	\$540	\$0	\$0
PROFESSIONAL SERVICES			
OTHER CHARGES	\$0	\$266,154	\$392,227
REPAIR & CONSTR.			
POSITIONS (#)			
TOTAL	\$540	\$266,154	\$392,227

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 17-18, FY 18-19 and FY 19-20. In FY 17-18, \$540 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 17-18	FY 18-19	FY 19-20
STATE GENERAL FUND	\$270	\$62,000	\$95,827
SELF-GENERATED			
FEDERAL FUND	\$270	\$204,154	\$296,400
OTHER (Specify)			
Total	\$540	\$266,154	\$392,227

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 17-18	FY 18-19	FY 19-20
STATE GENERAL FUND			
AGENCY SELF-GENERATED			
RESTRICTED FUNDS*			
FEDERAL FUNDS	\$270	\$204,154	\$296,400
LOCAL FUNDS			
Total	\$270	\$204,154	\$296,400

*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 17-18, FY 18-19 and FY 19-20. In FY 17-18, \$270 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.)

In compliance with U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services mandates, this proposed rule amends the provisions governing the Pharmacy Benefits Management Program to revise the reimbursement methodology for physician-administered drugs in a physician office setting in order to bring the rates into alignment with the 2018 Louisiana Medicare rate, and to incorporate a mechanism for periodic updates to the rates.

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

This proposed Rule will impact payments to providers due to the adjustment to current pricing for some physician-administered drugs. It is anticipated that implementation of this proposed rule will increase programmatic expenditures in the Pharmacy Benefits Management Program by approximately \$266,154 for FY 18-19 and \$392,227 for FY 19-20.

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.