NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Pharmacy Benefits Management Program
Reimbursement for Clotting Factor
(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) requires states to use reimbursement rates that meet actual acquisition costs. In compliance with CMS requirements, the Department of Health, Bureau of Health Services Financing proposes to amend the provisions governing methods of payment in the Pharmacy Benefits Management Program in order to: 1) change the reimbursement methodology for clotting factor products to a state generated actual acquisition cost (AAC) ingredient cost and a unit based professional dispensing fee; and 2) limit clotting factor products to pharmacy claims only.

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. – I.2.b. ...

J. Clotting Factor. Pharmacy claims for clotting factor will be reimbursed using a state generated actual acquisition cost (AAC) ingredient cost and a unit based professional dispensing fee reimbursement methodology.

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 44:1020 (June 2018), LR 45:571 (April 2019), LR 45:665 (May 2019), LR 46:35 (January 2020), LR 49:

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.

Family Impact Statement

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.

Poverty Impact Statement

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.

Small Business Impact Statement

In compliance with the Small Business Protection Act, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule may have an adverse impact on small businesses, as described in the Act if the reimbursement methodology change reduces payments to these providers. With the resources available to the department, a regulatory flexibility analysis has been prepared in order to consider methods to minimize the potential adverse impact on

small businesses. The department has determined that there is no less intrusive or less costly alternative method of achieving the intended purpose since the changes are a result of CMS requirements.

Provider Impact Statement

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 this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, but may increase direct or indirect cost to the provider to provide the same level of service due to the decrease in Medicaid reimbursement for clotting factor products. This proposed Rule may also have a negative impact on the provider's ability to provide the same level of service as described in HCR 170 if the reduction in payments adversely impacts the provider's financial standing.

Public Comments

Interested persons may submit written comments to Tara A. LeBlanc, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. Ms. LeBlanc is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on June 29, 2023.

Public Hearing

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 June 9, 2023. If the criteria set forth in R.S. 49:961(B)(1) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on June 29, 2023 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 Allen Enger at (225) 342-1342 after June 9, 2023. 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.

Dr. Courtney N. Phillips

Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Veronica Dent
Dept.: Health
Phone: 342-3238
Office: Bureau of Health Services Financing
Return Address: P.O. Box 91030
Baton Rouge, LA
Rule Title: Pharmacy Benefits Management Program
Reimbursement for Clotting Factor
Date Rule Takes Effect: August 20, 2023

SUMMARY
(Use complete sentences)

In accordance with Section 961 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 STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND 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 increase state costs by approximately $270 for FY 22-23 and reduce state costs by approximately $1,486,885 for FY 23-24 and $1,240,878 for FY 24-25. It is anticipated that $540 ($270 SGF and $270 FED) will be expended in FY 22-23 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 reduce revenue collections of statutory dedicated revenue from the Medical Assistance Trust Fund by approximately $193,646 for FY 23-24 and $464,750 for FY 24-25. In addition, this proposed rule will increase federal revenue collections by approximately $270 for FY 22-23 and reduce federal revenue collections by approximately $6,819,469 for FY 23-24 and $6,794,372 for FY 24-25. It is anticipated that $270 will be collected in FY 22-23 for the federal share of the expense for promulgation of this proposed rule and the final rule.

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

This proposed rule amends the provisions governing the methods of payment in the Pharmacy Benefits Management Program in order to: 1) change the reimbursement methodology for clotting factor products to a state generated actual acquisition cost (AAC) ingredient cost and a unit based professional dispensing fee; and 2) limit clotting factor products to pharmacy claims only, in compliance with U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) requirements. Implementation of this proposed rule is anticipated to result in decreased Medicaid reimbursement for clotting factor products and may have an adverse impact on pharmacy providers and small businesses if the reimbursement methodology change reduces payments to these providers. It is anticipated that this proposed rule will decrease expenditures in the Medicaid program by approximately $8,500,000 for FY 23-24 and $8,500,000 for FY 24-25.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Tara A. LeBlanc
Signature of Agency Head or Designee

Tara A. LeBlanc, Medicaid Executive Director
Typed Name & Title of Agency Head or Designee

Date of Signature

Evan Brasseaux, Interim Deputy Fiscal Officer
Legislative Fiscal Officer or Designee

5/9/23
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 deliberation 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 methods of payment in the Pharmacy Benefits Management Program in order to: 1) change the reimbursement methodology for clotting factor products to a state generated actual acquisition cost (AAC) ingredient cost and a unit based professional dispensing fee; and 2) limit clotting factor products to pharmacy claims only, in compliance with U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) requirements.

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

The U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) requires states to use reimbursement rates that meet actual acquisition costs. In compliance with CMS requirements, the Department of Health, Bureau of Health Services Financing proposes to amend the provisions governing methods of payment in the Pharmacy Benefits Management Program in order to: 1) change the reimbursement methodology for clotting factor products to a state generated actual acquisition cost (AAC) ingredient cost and a unit based professional dispensing fee; and 2) limit clotting factor products to pharmacy claims only.

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 result in an increase in costs to the Medicaid program by approximately $540 for FY 22-23 and a savings of approximately $8,500,000 in FY 23-24 and $8,500,000 in FY 24-25. In FY 22-23, $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) _____ Yes. If yes, attach documentation.

(b) _____ NO. If no, provide justification as to why this rule change should be published at this time

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

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

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

COSTS	FY 23	FY 24	FY 25
Personal Services			
Operating Expenses	$540	$0	$0
Professional Services			
Other Charges	$0	($8,500,000)	($8,500,000)
Equipment			
Major Repairs & Constr.			
TOTAL	$540	($8,500,000)	($8,500,000)
POSITIONS (#)			

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 savings reflected above for FY 23-24 are the estimated decreases in expenditures in the Medicaid program. In FY 22-23, $540 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 23	FY 24	FY 25
State General Fund	$270	($1,486,885)	($1,240,878)
Agency Self-Generated			
Dedicated	$0	($193,646)	($464,750)
Federal Funds	$270	($6,819,469)	($6,794,372)
Other (Specify)			
TOTAL	$540	($8,500,000)	($8,500,000)

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 THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments 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.

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

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

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

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

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

REVENUE INCREASE/DECREASE	FY 23	FY 24	FY 25
State General Fund			
Agency Self-Generated			
Dedicated Funds*	$0	($193,646)	($464,750)
Federal Funds	$270	($6,819,469)	($6,794,372)
Local Funds			
TOTAL	**$270**	**($7,013,115)**	**($7,259,122)**

*Specify the particular fund being impacted.

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

The amounts reflected above are the estimated decreases in statutory dedicated funds from the Medical Assistance Trust Fund and in federal revenue collections for FY 23-24 and FY 24-25. In FY 22-23, $270 will be collected for the federal share of the administrative expense for promulgation of this proposed rule and the final rule.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS

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

This proposed rule amends the provisions governing the methods of payment in the Pharmacy Benefits Management Program in order to: 1) change the reimbursement methodology for clotting factor products to a state generated actual acquisition cost (AAC) ingredient cost and a unit based professional dispensing fee; and 2) limit clotting factor products to pharmacy claims only, in compliance with U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) requirements.

B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

Implementation of this proposed rule is anticipated to result in decreased Medicaid reimbursement for clotting factor products and may have an adverse impact on pharmacy providers and small businesses if the reimbursement methodology change reduces payments to these providers. It is anticipated that this proposed rule will decrease expenditures in the Medicaid program by approximately $8,500,000 for FY 23-24 and $8,500,000 for FY 24-25.

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.