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

RULE TITLE: Pharmacy Benefits Management Program

Reimbursement for Clotting Factor

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.