

NOTICE OF INTENT

Department of Health Bureau of Health Services Financing

Hospital Services Coverage of Gene Therapies for Sickle Cell Disease (LAC 50:V.120)

The Department of Health, Bureau of Health Services Financing proposes to adopt LAC 50:V.120 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.

Effective July 1, 2025 the Department of Health, Bureau of Health Services Financing adopted cell and gene therapy model that provides additional supplemental and federal rebates for gene therapies for sickle cell disease. To receive these rebates, the department amended the provisions governing inpatient hospital services to allow reimbursement for gene therapies for sickle cell disease outside the per diem rate and paid based on the actual acquisition cost. This proposed Rule is being promulgated to continue the provisions of the July 1, 2025 Emergency Rule (*Louisiana Register*, Volume 51, Number 7).

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

Part V. Hospital Services

Subpart 1. Inpatient Hospitals Services

Chapter 1. General Provisions

§120. Coverage of Gene Therapies for Sickle Cell Disease

A. Effective for dates of service on or after July 1, 2025, gene therapies for sickle cell disease administered during an inpatient stay shall be reimbursed outside of the per diem rate for the inpatient stay. Claims for gene therapies for sickle cell disease shall be reimbursed at actual acquisition cost.

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 51:

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 Analysis

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 will have no impact on small businesses.

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 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.

Public Comments

Interested persons may submit written comments to Kimberly Sullivan, JD, Bureau of Health Services Financing, P.O. Box

91030, Baton Rouge, LA 70821-9030. Ms. Sullivan is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is August 19, 2025.

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 August 11, 2025. 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 August 28, 2025 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 August 11, 2025. 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.

Bruce D. Greenstein

Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Hospital Services

Coverage of Gene Therapies for Sickle Cell Disease

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 25-26. It is anticipated that \$432 (\$216 SGF and \$216 FED) will be expended in FY 25-26 for the state's administrative expense for promulgation of the proposed rule and the final rule.

This proposed rule continues the provisions of the July 1, 2025, Emergency Rule which amended the provisions governing inpatient hospital services to allow reimbursement for gene therapies for sickle cell disease to be paid outside the per diem rate and paid in actual acquisition cost. Changing the reimbursement method allows the providers to take advantage of federal and supplemental rebates, which will result in a savings.

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

There is no known impact on revenue collections of state or local governmental units as a result of the implementation of this proposed rule other than the federal share of the promulgation costs for FY 25-26. This proposed rule is being

promulgated to take advantage of federal and supplemental rebates. The amount the providers will collect in rebates is indeterminable. It is anticipated the \$216 will be collected in FY 25-26 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 continues the provisions of the July 1, 2025 Emergency Rule which amended the provisions governing inpatient hospital services to allow reimbursement for gene therapies for sickle cell disease to be paid outside the per diem rate and paid in actual acquisition cost. Changing the reimbursement method allows the providers to take advantage of federal and supplemental rebates, which will offset their costs. This proposed rule will not affect small businesses.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This proposed rule has no known effect on competition and employment.