

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

**RULE TITLE: Experimental Procedures
Routine Care for Beneficiaries in Clinical Trials**

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT 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 21-22. It is anticipated that \$432 (\$216 SGF and \$216 FED) will be expended in FY 21-22 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 21-22. It is anticipated that \$216 will be collected in FY 21-22 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 NONGOVERNMENTAL GROUPS (Summary)

This proposed rule amends the provisions governing experimental procedures in order to align the provisions governing routine care for beneficiaries in clinical trials with federal requirements specified in the American Rescue Plan Act. The proposed rule does not change existing policy, but it ensures that the terminology and specifications in the Louisiana Administrative Code are in alignment with requirements of the Social Security Act. It is anticipated that implementation of this proposed rule will not result in costs to providers in FY 21-22, FY 22-23, and FY 23-24 but will be beneficial by ensuring that the language in the administrative rule aligns with federal law.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Patrick Gillies
Medicaid Executive Director
2206#052

Evan Brasseaux
Interim Deputy Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

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

Home Health Program—Durable Medical Equipment
Enteral Formula Reimbursement
(LAC 50:XIII.10301)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XIII.10301 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 proposes to amend the provisions governing reimbursement for durable medical equipment in the Home Health Program in order to revise the methodology used to set the rates for enteral formulas and allow reimbursement under the standard procedure codes on the Louisiana Medicaid fee schedule.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

Part XIII. Home Health Program

Subpart 3. Medical Equipment, Supplies and Appliances

Chapter 103. Reimbursement Methodology

§10301. General Provisions

A. - F. ...

G. Effective for dates of service on or after October 1, 2022, fees for enteral formulas will be set at 90 percent of 2021 Rural Medicare fees. For enteral formulas without a corresponding Medicare fee, the Medicaid fees will be set at the lowest fee at which the item has been determined to be widely available based on a review of similar formulas, usual and customary fees charged in the community, and other Medicaid states.

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, Bureau of Health Services Financing, LR 35:1894 (September 2009), amended LR 36:1247 (June 2010), LR 36:2041 (September 2010), LR 39:1050 (April 2013), amended by the Department of Health, Bureau of Health Services Financing, LR 48:

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 a positive impact on family functioning, stability and autonomy as described in R.S. 49:972 as it will allow recipients access to a wider selection of enteral formulas.

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 a positive impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973 as it will allow recipients access to a wider selection of enteral formulas.

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 be beneficial to small businesses as it simplifies the prior authorization process for durable medical equipment providers and increases access to a wider selection of enteral formulas for their patients.

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 Patrick Gillies, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821—9030. Mr. Gillies is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on August 1, 2022.

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 July 11, 2022. 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 July 28, 2022 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 July 11, 2022. 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.

Dr. Courtney N. Phillips
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Home Health Program—Durable Medical Equipment—Enteral Formula Reimbursement

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

It is anticipated that implementation of this proposed rule will have an indeterminable fiscal impact to the state for FY 21-22, FY 22-23 and FY 23-24, since enteral products will now be grouped and reimbursed under categories. It is anticipated that \$540 (\$270 SGF and \$270 FED) will be expended in FY 21-22 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 an indeterminable impact on revenue collections for FY 21-22, FY 22-23 and FY 23-24. It is anticipated that \$270 will be collected in FY 21-22 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 NONGOVERNMENTAL GROUPS (Summary)

The proposed rule amends the provisions governing reimbursement for durable medical equipment in the Home Health Program in order to revise the methodology used to set the rates for Enteral Formulas and allow reimbursement for these products under the standard procedure codes on the

Louisiana Medicaid fee schedule. The proposed rule will allow reimbursement for these products under specific categories on the fee schedule and align Louisiana Medicaid's reimbursement with other states and Medicare. Implementation of this proposed rule will allow beneficiaries greater access to a wider selection of these products to meet their medical needs. Providers will also benefit since it streamlines the prior authorization process and increases access to products for their patients. It is anticipated that implementation of this proposed rule will result in an indeterminable net impact on expenditures in the Medicaid program for FY 21-22, FY 22-23, and FY 23-24, since individual products will be grouped and paid under categories.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Patrick Gillies
Medicaid Executive Director
2206#053

Evan Brasseaux
Interim Deputy Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health Bureau of Health Services Financing

Home Health Program—Emergency Provisions (LAC 50:XIII.104)

The Department of Health, Bureau of Health Services Financing proposes to adopt LAC 50:XIII.104 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 proposes to adopt provisions in the Home Health Program in order to temporarily allow non-physician practitioners to order and review home health services in the event of a federal or state declared emergency or disaster.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

Part XIII. Home Health Program

Subpart 1. Home Health Services

Chapter 1. General Provisions

§104. Emergency Provisions

A. In the event that the federal or state government declares an emergency or disaster, the Medicaid Program may temporarily allow non-physician practitioners (advanced practice registered nurses and physician assistants) to order and review home health services, including the completion of associated documentation, if such action is deemed necessary to insure sufficient services are available to meet beneficiaries' needs.

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 48:

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.