

NOTICE OF INTENT

Department of Health Bureau of Health Services Financing

Experimental Procedures Routine Care for Beneficiaries in Clinical Trials (LAC 50:I.305)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:I.305 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 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.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

Part I. Administration

Subpart 1. General Provisions

Chapter 3. Experimental Procedures

§305. Routine Care for ~~Recipients~~ Beneficiaries in Clinical Trials

A. ~~This rule applies to any person or entity prescribing or reviewing a request for Louisiana Medicaid covered services~~

~~and to all providers of these services who are enrolled in, or registered with, the Louisiana~~ The Medicaid program shall cover routine patient costs for items and services furnished in connection with participation in a qualifying clinical trial in accordance with section 1905(gg) of the Social Security Act.

~~B. Definitions~~

~~Clinical Trials—biomedical or behavioral research studies on human participants designed to answer specific questions about biomedical or behavioral interventions, including new treatments and known interventions that warrant further study and comparison.~~

~~C. Coverage. Louisiana Medicaid reimburses for services as a result of a beneficiary participating in a clinical trial in accordance with the service-specific coverage policy when the services:~~

~~1. would otherwise be provided to a beneficiary who is not participating in a clinical trial;~~

~~2. are not unique to the experimental or investigational treatment; and~~

~~3. are not covered by the clinical trial sponsor.~~ B.

- C. Repealed.

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 46:796 (June 2020), amended 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 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 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