

NOTICE OF INTENT

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

**Routine Patient Care and Clinical Trials
(LAC 50:I.305)**

The Department of Health, Bureau of Health Services Financing proposes to adopt 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 adopt provisions governing routine care for recipients in clinical trials in order to clarify the requirements for reimbursement for medically necessary non-experimental/investigational treatments that recipients participating in clinical trials would otherwise receive under the Louisiana Medicaid program.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

Part I. Administration

Subpart 1. General Provisions

Chapter 3. Experimental Procedures

§305. Routine Care for Recipients 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 Medicaid program.

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 recipient participating in a clinical trial in accordance with the service-specific coverage policy when the services:

1. would otherwise be provided to a recipient 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.

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:

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 Act 820 of the 2008 Regular Session of the Louisiana Legislature, 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, as described in R.S. 49:965.2 et seq.

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 Erin Campbell, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. Ms. Campbell is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on April 29, 2020.

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 April 9, 2020. 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 April 29, 2020 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 April 9, 2020. 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.

Stephen R. Russo, JD

Interim Secretary