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

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Veronica Dent

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Return Address: PO Box 91030
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Rule Title: Routine Patient Care and Clinical Trials

Date Rule Takes Effect: June 20, 2020

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

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 19-20. It is anticipated that $540 ($270 SGF and $270 FED) will be expended in FY 19-20 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 19-20. It is anticipated that $270 will be collected in FY 19-20 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 adopts 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. Although these treatments are currently reimbursed by Louisiana Medicaid, the language in the current administrative Rule is unclear. This proposed Rule is necessary in order to promulgate the provisions governing these services clearly in the Louisiana Administrative Code and to ensure that the language in the administrative Rule reflects current practices. Recipients and providers will benefit from clarification that these covered services are already reimbursable for participants in clinical trials. It is anticipated that implementation of this proposed Rule will not result in any economic impact to Medicaid providers or small businesses in FY 19-20, FY 20-21, and FY 21-22.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)
This rule has no known effect on competition and employment.

Signature of Agency Head or Designee

Legislative Fiscal Officer or Designee

Erin Campbell, Acting Medicaid Director
Typed Name & Title of Agency Head or Designee

3/10/2020
Date of Signature

3/10/20
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

This proposed rule adopts 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.

B. Summarize the circumstances, which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

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.

C. Compliance with Act 11 of the 1986 First Extraordinary Session

(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

No. 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 19-20. In FY 19-20, $540 is included for the state's administrative expense for promulgation of this proposed rule and the final rule.

(2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) _____ Yes. If yes, attach documentation.

(b) _____ NO. If no, provide justification as to why this rule change should be published at this time

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 20	FY 21	FY 22
Personal Services			
Operating Expenses	$540	$0	$0
Professional Services			
Other Charges			
Equipment			
Major Repairs & Constr.			
TOTAL	**$540**	**$0**	**$0**
POSITIONS (#)			

2. Provide a narrative explanation of the costs or savings shown in "A. 1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

   In FY 19-20, $540 will be spent for the state's administrative expense for promulgation of this proposed rule and the final rule.

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 20	FY 21	FY 22
State General Fund	$270	$0	$0
Agency Self-Generated			
Dedicated			
Federal Funds	$270	$0	$0
Other (Specify)			
TOTAL	**$270**	**$0**	**$0**

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

   Yes, sufficient funds are available to implement this rule.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

   This proposed rule has no known impact on local governmental units.

2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

   There is no known impact on the sources of local governmental unit funding.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

REVENUE INCREASE/DECREASE	FY 20	FY 21	FY 22
State General Fund			
Agency Self-Generated			
Dedicated Funds*			
Federal Funds	$270	$0	$0
Local Funds			
TOTAL	**$270**	**$0**	**$0**

*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

In FY 19-20, $270 will be collected for the federal share of the administrative expense for promulgation of this proposed rule and the final rule.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS

A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

This proposed rule adopts 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. Although these treatments are currently reimbursed by Louisiana Medicaid, the language in the current administrative Rule is unclear. This proposed Rule is necessary in order to promulgate the provisions governing these services clearly in the Louisiana Administrative Code and to ensure that the language in the administrative Rule reflects current practices. Recipients and providers will benefit from clarification that these covered services are already reimbursable for participants in clinical trials.

B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

It is anticipated that implementation of this proposed Rule will not result in any economic impact to Medicaid providers or small businesses in FY 19-20, FY 20-21, and FY 21-22.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

This rule has no known effect on competition and employment.