FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Office of Behavioral Health Children and Adult Mental Health Services

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 19-20. It is anticipated that \$1,296 (\$648 SGF and \$648 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 \$648 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 OR NONGOVERNMENTAL GROUPS (Summary)

This proposed rule amends the provisions governing children and adult mental health services in order to update the Rule language to reflect current terminology and practices and to change the treatment plan review requirement from 365 to 180 days. This Rule is anticipated to have no impact on small businesses. It is anticipated that implementation of this proposed Rule will not result in any increase or decrease in payments to behavioral health providers in FY 19-20, FY 20-21, and FY 21-22 but will be beneficial by ensuring that the provisions are accurately promulgated in the Louisiana Administrative Code.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Erin Campbell Acting Medicaid Director 2003#047 Evan Brasseaux Staff Director Legislative Fiscal Office

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.

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 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 **RULE TITLE: Routine Patient Care and 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 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.

ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL 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 nonexperimental/investigational treatments recipients that 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, FŶ 20-21, and FY 21-22.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Erin Campbell Acting Medicaid Director 2003#050

Evan Brasseaux Staff Director Legislative Fiscal Office

NOTICE OF INTENT

Department of Health Bureau of Health Services Financing

Telemedicine (LAC 50:I.501)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:I.501 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

The Department of Health, Bureau of Health Services Financing proposes to amend the provisions governing telemedicine in order to clarify that there are no limitations as to the telemedicine originating site.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE Part I. Administration

Subpart 1. General Provisions

Chapter 5. Telemedicine §501. Introduction

A. Telemedicine is the use of an interactive audio and video telecommunications system to permit real time communication between a distant site health care practitioner and the recipient. There is no restriction on the originating site (i.e., where the recipient is located) and it can include, but is not limited to, healthcare facility, school, or the recipient's home.

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, Office of the Secretary, Bureau of Health Services Financing, LR 31:2032 (August 2005), amended by the Department of Health, Bureau of Health Services Financing, LR

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.