

NOTICE OF INTENT

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

**End Stage Renal Disease Facilities
Reimbursement for Independent Laboratory Services
(LAC 50:X1.6901)**

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:X1.6901 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.

Independent laboratories contracted with end stage renal disease (ESRD) facilities are currently reimbursed by the ESRD facility for covered non-routine laboratory services provided to Medicaid recipients. The Department of Health, Bureau of Health Services Financing now proposes to amend the provisions governing reimbursement for ESRD facilities in order to allow contracted independent laboratories to bill the Medicaid program directly for the provision of covered non-routine laboratory services instead of receiving reimbursement from the ESRD facility.

Title 50

**PUBLIC HEALTH - MEDICAL ASSISTANCE
Part XI. Clinic Services
Subpart 9. End Stage Renal Disease Facilities**

Chapter 69. Reimbursement

§6901. General Provisions

A. ...

B. Covered non-routine dialysis services, continuous ambulatory peritoneal dialysis (CAPD), continuous cycling peritoneal dialysis (CCPD), epogen (EPO) and injectable drugs are reimbursed separately from the composite rate.

1. Covered non-routine laboratory services may be billed by either the ESRD facility or the facility's contracted outside laboratory.

C. - G. ...

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 30:1022 (May 2004), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 35:1891 (September 2009), LR 36:2040 (September 2010), LR 37:1599 (June 2011), LR 39:1284 (May 2013), amended 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 may be beneficial to small businesses, as described in R.S. 49:965.2 et seq. since independent laboratories contracted with end stage renal disease facilities will have the ability to bill, and be reimbursed by the Medicaid program, for providing non-routine covered services.

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, but may reduce the direct or indirect cost to the provider to provide the same level of service, and may enhance the provider's ability to provide the same level of service as described in HCR 170 since independent laboratories contracted with end stage renal disease facilities will have the ability to bill, and be reimbursed by, the Medicaid program for providing non-routine covered services.

Public Comments

Interested persons may submit written comments to Ruth Johnson, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. Ms. Johnson is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on August 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 August 10, 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 August 27, 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 August 10, 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.

Dr. Courtney N. Phillips

Secretary

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

Person Preparing Statement:	<u>Veronica Dent</u>	Dept.:	<u>Health</u>
Phone:	<u>342-3238</u>	Office:	<u>Bureau of Health Services Financing</u>
Return Address:	<u>PO Box 91030</u>	Rule Title	<u>End Stage Renal Disease Facilities</u>
	<u>Baton Rouge, LA</u>		<u>Reimbursement for Independent Laboratory Services</u>
		Date Rule Takes Effect:	<u>October 20, 2020</u>

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 result in increased state costs of approximately \$37,588 for FY 20-21, \$37,318 for FY 21-22 and \$37,318 for FY 22-23. It is anticipated that \$540 (\$270 SGF and \$270 FED) will be expended in FY 20-21 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 increase federal revenue collections by approximately \$77,005 for FY 20-21, \$76,735 for FY 21-22, and \$76,735 for FY 22-23. It is anticipated that \$270 will be collected in FY 20-21 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 amends the provisions governing reimbursement for end stage renal disease (ESRD) facilities in order to allow contracted independent laboratories to bill the Medicaid program directly for the provision of covered non-routine laboratory services instead of receiving reimbursement from the ESRD facility. Providers will benefit from implementation of this proposed Rule since they will no longer have to seek reimbursement from the contracted ESRD facility for the provision of these services. While the ESRD facilities have the ability to bill for these non-routine laboratory services, they have not historically done so; therefore, implementation of this proposed Rule will result in increased costs. It is anticipated that implementation of this proposed Rule will increase expenditures for ESRD services by approximately \$114,053 for FY 20-21, \$114,053 for FY 21-22, and \$114,053 for FY 22-23 since independent laboratories contracted with ESRD facilities will have the ability to bill, and be reimbursed directly by, the Medicaid program for providing non-routine covered services.

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

Ruth Johnson, Medicaid Executive Director
Typed Name & Title of Agency Head or Designee

7/9/20
Date of Signature

7/9/20
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 amends the provisions governing reimbursement for end stage renal disease (ESRD) facilities in order to allow contracted independent laboratories to bill the Medicaid program directly for the provision of covered non-routine laboratory services instead of receiving reimbursement from the ESRD facility.

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

Independent laboratories contracted with end stage renal disease (ESRD) facilities are currently reimbursed by the ESRD facility for covered non-routine laboratory services provided to Medicaid recipients. The Department of Health, Bureau of Health Services Financing now proposes to amend the provisions governing reimbursement for ESRD facilities in order to allow contracted independent laboratories to bill the Medicaid program directly for the provision of covered non-routine laboratory services instead of receiving reimbursement from the ESRD facility.

- 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.

Yes. It is anticipated that implementation of this proposed rule will result in increased programmatic costs of approximately \$114,593 for FY 20-21, \$114,053 for FY 21-22, and \$114,053 for FY 22-23. In FY 20-21, \$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) X NO. If no, provide justification as to why this rule change should be published at this time

Act 10 of the 2019 Regular Session of the Louisiana Legislature allocated funds to the Medical Vendor Program for payments to providers and the operation of the Medicaid Program, and thereby, authorizes the expenditure of these funds. The proposed Rule ensures that contracted independent laboratories will be reimbursed for the provision of non-routine laboratory services to end stage renal disease (ESRD) patients by allowing these providers to bill the Medicaid program directly for the services rather than seeking reimbursement from the ESRD facility.

**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 21	FY 22	FY 23
Personal Services			
Operating Expenses	\$540	\$0	\$0
Professional Services			
Other Charges	\$114,053	\$114,053	\$114,053
Equipment			
Major Repairs & Constr.			
TOTAL	\$114,593	\$114,053	\$114,053
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.

The expenses reflected above are the estimated increases in expenditures in the Medicaid program. In FY 20-21, \$540 is included 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 21	FY 22	FY 23
State General Fund	\$37,588	\$37,318	\$37,318
Agency Self-Generated			
Dedicated			
Federal Funds	\$77,005	\$76,735	\$76,735
Other (Specify)			
TOTAL	\$114,593	\$114,053	\$114,053

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?

<u>REVENUE INCREASE/DECREASE</u>	<u>FY 20</u>	<u>FY 21</u>	<u>FY 22</u>
State General Fund			
Agency Self-Generated			
Dedicated Funds*			
Federal Funds	\$77,005	\$76,735	\$76,735
Local Funds			
TOTAL	\$77,005	\$76,735	\$76,735

*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.

The amounts reflected above are the estimated increase in the federal share of programmatic expenditures for the Medicaid program. In FY 20-21, \$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 amends the provisions governing reimbursement for end stage renal disease (ESRD) facilities in order to allow contracted independent laboratories to bill the Medicaid program directly for the provision of covered non-routine laboratory services instead of receiving reimbursement from the ESRD facility. Providers will benefit from implementation of this proposed Rule since they will no longer have to seek reimbursement from the contracted ESRD facility for the provision of these services. While the ESRD facilities have the ability to bill for these non-routine laboratory services, they have not historically done so; therefore, implementation of this proposed Rule will result in increased costs.

- 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 increase expenditures for ESRD services by approximately \$114,050 for FY 20-21, \$114,050 for FY 21-22, and \$114,050 for FY 22-23 since independent laboratories contracted with ESRD facilities will have the ability to bill, and be reimbursed directly by, the Medicaid program for providing non-routine covered services.

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.