

NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Laboratory and Radiology Services
Termination of Coverage for Proton Beam Radiation Therapy
(LAC 50:XIX.4334)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XIX.4334 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.

The Department of Health, Bureau of Health Services Financing currently provides Medicaid coverage and reimbursement for proton beam radiation therapy services under the laboratory and radiology benefit. Proton beam radiation is a type of external radiation therapy utilized in the treatment of malignant and benign tumors and arteriovenous malformations. National best practice standards indicate that the therapy is most appropriate for treatment of tumors in individuals who are under the age of 21.

As the Medicaid Program continues to look for cost containment measures to ensure fiscal responsibility, we

also strive to ensure Medicaid recipients receive the most appropriate, quality services. Therefore, it is imperative that our coverage policies align with best practice standards which is a fiscally sound approach to health care service delivery.

Hence, the department proposes to amend the provisions governing laboratory and radiology services to terminate coverage and reimbursement of proton beam radiation therapy for recipients 21 years of age and older. The services will continue to be available for recipients under the age of 21 when deemed medically necessary.

Title 50
PUBLIC HEALTH-MEDICAL ASSISTANCE
Part XIX. Other Healthcare Services
Subpart 3. Laboratory and Radiology Services

Chapter 43. Billing and Reimbursement

Subchapter B. Reimbursement

§4334. Radiology Services

A. - K.3. ...

L. Effective for dates of service on or after February 20, 2018, or upon promulgation of this Rule, the Medicaid Program terminates coverage and reimbursement for proton beam radiation therapy (PBRT) for recipients 21 years of age and older.

1. For recipients under the age of 21, coverage and reimbursement shall be provided when PBRT services are deemed medically necessary.

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, Bureau of Health Services Financing, LR 30:1026 (May 2004), amended LR 35:1898 (September 2009), amended LR 36:1248 (June 2010), LR 36:2563 (November 2010), LR 37:3029 (October 2011), LR 39:1284 (May 2013), LR 41:540 (March 2015), amended by the Department of Health, Bureau of Health Services Financing, LR 44:

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.

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 or autonomy as described in R.S. 49:972.

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.

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 have a minimal increase in direct or indirect cost to the provider to provide the same level of service due to the termination of Medicaid payments for these services for recipients 21 and over. The proposed Rule may also have a minimal adverse impact on the provider's ability to provide the same level of service as described in HCR 170 if the reduction in payments adversely impacts the provider's financial standing.

Interested persons may submit written comments to Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030 or by email to MedicaidPolicy@la.gov. Ms. Steele is responsible for

responding to inquiries regarding this proposed Rule. A public hearing on this proposed Rule is scheduled for Thursday, December 28, 2017 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Rebekah E Gee MD, MPH

Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person

Preparing

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Office: Bureau of Health Services
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Address: Baton Rouge, LA

Rule Title: Laboratory and Radiology
Services
Termination of Coverage for
Proton Beam Radiation Therapy

Date Rule Takes Effect: February 20, 2018

SUMMARY

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 summary statements, based on the attached worksheets, 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 the implementation of this proposed rule will result in estimated state programmatic savings of approximately \$4,019 for FY 17-18, \$11,678 for FY 18-19 and \$11,678 FY 19-20. It is anticipated that \$540 (\$270 SGF and \$270 FED) will be expended in FY 17-18 for the state's administrative expense for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 63.34 percent in FY 17-18, and 64.23 in FY 18-19 and FY 19-20.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

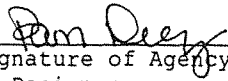
It is anticipated that the implementation of this proposed rule will decrease federal revenue collections by approximately \$7,140 for FY 17-18, \$20,969 for FY 18-19 and \$20,969 for FY 19-20. It is anticipated that \$270 will be expended in FY 17-18 for the federal administrative expenses for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 63.34 percent in FY 17-18, and 64.23 in FY 18-19 and FY 19-20.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

This proposed Rule amends the provisions governing laboratory and radiology services to terminate coverage and reimbursement of proton beam radiation therapy (PBRT) for recipients 21 years of age and older. Medicaid recipients age 21 and over may be impacted by this proposed Rule as alternative treatment options may be required due to termination of coverage for this service. It is anticipated that implementation of this proposed rule may have an economic impact on PRBT providers and will decrease Medicaid programmatic expenditures for laboratory and radiology services by approximately \$11,699 for FY 17-18, \$32,647 for FY 18-19 and \$32,647 for FY 19-20.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)


It is anticipated that the implementation of this proposed rule will not have an effect on competition.

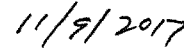


Signature of Agency Head
or Designee



Legislative Fiscal Officer
or Designee


Wen Steele, Medicaid Director
Typed name and Title of
Agency Head or Designee



Date of Signature



LDH/BHSF Budget Head



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 deliberations 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 laboratory and radiology services to terminate coverage and reimbursement of proton beam radiation therapy (PBRT) for recipients 21 years of age and older.

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

The Department of Health, Bureau of Health Services Financing currently provides Medicaid coverage and reimbursement for proton beam radiation therapy services under the laboratory and radiology benefit. Proton beam radiation is a type of external radiation therapy utilized in the treatment of malignant and benign tumors and arteriovenous malformations. National best practice standards indicate that the therapy is most appropriate for treatment of tumors in individuals who are under the age of 21.

As the Medicaid Program continues to look for cost containment measures to ensure fiscal responsibility, we also strive to ensure Medicaid recipients receive the most appropriate, quality services. Therefore, it is imperative that our coverage policies align with best practice standards which is a fiscally sound approach to health care service delivery.

Hence, the department proposes to amend the provisions governing laboratory and radiology services to terminate coverage and reimbursement of proton beam radiation therapy for recipients 21 years of age and older. The services will continue to be available for recipients under the age of 21 when deemed medically necessary.

- 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, this proposed rule will result in a reduction in programmatic expenditures by approximately \$11,159 for FY 17-18, \$32,647 for FY 18-19 and \$32,647 for FY 19-20. In FY 17-18, \$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) _____ If yes, attach documentation.
(b) _____ If no, provide justification as to why this rule change should be published at this time.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

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

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

COST	FY 17-18	FY 18-19	FY 19-20
PERSONAL SERVICES			
OPERATING EXPENSES	\$540	\$0	\$0
PROFESSIONAL SERVICES			
OTHER CHARGES	(\$11,699)	(\$32,647)	(\$32,647)
REPAIR & CONSTR.			
POSITIONS (#)			
TOTAL	(\$11,159)	(\$32,647)	(\$32,647)

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 decreases in programmatic expenditures in the Medicaid program. In FY 17-18, \$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 17-18	FY 18-19	FY 19-20
STATE GENERAL FUND	(\$4,019)	(\$11,678)	(\$11,678)
SELF-GENERATED			
FEDERAL FUND	(\$7,140)	(\$20,969)	(\$20,969)
OTHER (Specify)			
Total	(\$11,159)	(\$32,647)	(\$32,647)

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 THIS PROPOSED ACTION.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustment 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.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

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

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

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

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

REVENUE INCREASE/DECREASE	FY 17-18	FY 18-19	FY 19-20
STATE GENERAL FUND			
AGENCY SELF-GENERATED			
RESTRICTED FUNDS*			
FEDERAL FUNDS	(\$7,140)	(\$20,969)	(\$20,969)
LOCAL FUNDS			
Total	(\$7,140)	(\$20,969)	(\$20,969)

**Specify the particular fund being impacted*

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

The amounts reflected above are the estimated reductions in the federal share of programmatic expenditures for the Medicaid Program. In FY 17-18, \$270 is included for the federal expense for promulgation of this proposed rule and the final rule.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

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

This proposed Rule amends the provisions governing laboratory and radiology services to terminate coverage and reimbursement of proton beam radiation therapy (PBRT) for recipients 21 years of age and older.

- B. Also, provide an estimate of any revenue impact resulting from this rule or rule change to these groups.

Medicaid recipients age 21 and over may be impacted by this proposed Rule as alternative treatment options may be required due to termination of coverage for this service. It is anticipated that implementation of this proposed rule may have an economic impact on PRBT providers and will decrease Medicaid programmatic expenditures for laboratory and radiology services by approximately \$11,699 for FY 17-18, \$32,647 for FY 18-19 and \$32,647 for FY 19-20.

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.

It is anticipated that the implementation of this proposed rule will not have an effect on competition.