NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Pharmacy Benefits Management Program
Federal Upper Payment Limits and Physician-Administered Drugs Reimbursement
(LAC 50:XXIX.105 and 949)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.105 and §949 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 amended the provisions governing the Pharmacy Benefits Management Program in order to revise the reimbursement methodology for physician-administered drugs in a physician office setting to bring the rates current and to incorporate a mechanism for periodic updates to the rates in compliance with U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) requirements (*Louisiana Register*, Volume 44, Number 6). The department promulgated a Notice of Intent which proposed to amend the provisions governing pharmacy ingredient cost reimbursement in order to change the reimbursement methodology from average acquisition cost to the national average drug acquisition cost (*Louisiana*

Register, Volume 45, Number 1). The department subsequently determined that the Notice of Intent published in the January 20, 2019 edition of the *Louisiana Register* erroneously repealed the provisions governing federal upper payment limits.

The department now proposes to amend the provisions governing reimbursement in the Pharmacy Benefits Management Program in order to: 1) reinstate the federal upper payment limits provisions; 2) align the reimbursement methodology for physician-administered drugs in a physician office setting with the corresponding CMS-approved State Plan Amendment; and 3) ensure that these provisions are appropriately promulgated in the *Louisiana Administrative Code*.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XXIX. Pharmacy

Chapter 1. General Provisions

§105. Medicaid Pharmacy Benefits Management System Point of Sale—Prospective Drug Utilization Program

A. - B. ...

C. Covered Drug List. The list of covered drugs is managed through multiple mechanisms. Drugs in which the manufacturer entered into the Medicaid Drug Rebate Program with CMS are included in the list of covered drugs. National average drug acquisition cost (NADAC) and usual and customary charges

assist in managing costs on the covered drug list. Federal upper limits provide for dispensing of multiple source drugs at established limitations unless the prescribing practitioner specifies that the brand product is medically necessary for a patient. Establishment of co-payments also provides for management.

D. Reimbursement Management. The cost of pharmaceutical care is managed through NADAC of the ingredient or through wholesale acquisition cost (WAC) when no NADAC is assigned, and compliance with FUL regulations, the establishment of the professional dispensing fee, drug rebates and copayments. Usual and customary charges are compared to other reimbursement methodologies and the "lesser of" is reimbursed.

E. - L. ...

AUTHORITY NOTE: Promulgated in accordance with R.S, 36:254, Title XIX of the Social Security Act, and the 1995-96 General Appropriate Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1053 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1180 (June 2017), LR 43:1553 (August 2017), LR 45:

Chapter 9. Methods of Payment

Subchapter D. Maximum Allowable Costs

§949. Fee for Service Cost Limits

A. - B.1.a. ...

2. federal upper payment limits plus the professional dispensing fee; or

a. Repealed.

3. the provider's usual and customary charges to the general public not to exceed the department's "maximum payment allowed."

a. For purposes of these provisions, the term general public does not include any person whose prescriptions are paid by third-party payors, including health insurers, governmental entities, and Louisiana Medicaid.

C. Federal Upper Payment Limits for Multiple Source Drugs

1. Except for drugs subject to "physician certification", the Medicaid Program shall utilize listings established by the Centers for Medicare and Medicaid Services (CMS) that identify and set upper limits for multiple source drugs that meet all of the following requirements:

a. All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, Approved Drug Products with Therapeutic Equivalence Evaluations (including supplements or in successor publications).

b. At least three suppliers list the drug, which has been classified by the FDA as category "A" in the aforementioned publication based on listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

2. Medicaid shall utilize the maximum acquisition cost established by CMS in determining multiple source drug cost.

a. - c. Repealed.

3. The Medicaid Program shall provide pharmacists who participate in Medicaid reimbursement with updated lists reflecting:

a. the multiple source drugs subject to federal multiple source drug cost requirements;

b. the maximum reimbursement amount per unit; and

c. the date such costs shall become effective.

D. Physician Certifications

1. Limits on payments for multiple source drugs shall not be applicable when the prescriber certifies in his own handwriting that a specified brand name drug is medically necessary for the care and treatment of a recipient. Such certification may be written directly on the prescription or on a separate sheet which is dated and attached to the

prescription. A standard phrase in the prescriber's handwriting, such as "brand necessary" will be acceptable.

2. Any practice which precludes the prescriber's handwritten statement shall not be accepted as a valid certification. Such practices include, but are not limited to:

a. a printed box on the prescription blank that could be checked by the prescriber to indicate brand necessity;

b. a handwritten statement transferred to a rubber stamp and then stamped on the prescription blank; or

c. preprinted prescription forms using a facsimile of the prescriber's handwritten statement.

E. Fee for Service 340B Purchased Drugs. The department shall make payments for self-administered drugs that are purchased by a covered entity through the 340B program at the actual acquisition cost which can be no more than the 340B ceiling price plus the professional dispensing fee, unless the covered entity has implemented the Medicaid carve-out option, in which case 340B drugs should not be billed to or reimbursed by Medicaid. 340B contract pharmacies shall not bill 340B stock to Medicaid. Fee-for-service outpatient hospital claims for 340B drugs shall use a cost to charge methodology on the interim cost report and settled during final cost settlement. Federally qualified health center (FQHC) and rural health clinic (RHC)

claims for physician administered drugs shall be included in the all-inclusive T1015 encounter rate.

F. Federal Supply Schedule Drugs. Drugs acquired at federal supply schedule (FSS) and at a nominal price shall be reimbursed at actual acquisition cost plus a professional dispensing fee.

G. Indian Health Service All-Inclusive Encounter Rate. Pharmacy services provided by the Indian Health Service (IHS) shall be included in the encounter rate. No individual pharmacy claims shall be reimbursed to IHS providers.

H. Mail Order, Long-Term Care and Specialty Pharmacy. Drugs dispensed by mail order, long-term care and/or specialty pharmacies (drugs not distributed by a retail community pharmacy) will be reimbursed using the brand/generic drug reimbursement methodology.

1. - 2.b.iv. Repealed.

I. Physician-Administered Drugs. Medicaid-covered physician-administered drugs shall be reimbursed according to the Louisiana professional services fee schedule. Reimbursement shall be determined utilizing the following methodology, and periodic updates to the rates shall be made in accordance with the approved Louisiana Medicaid State Plan provisions governing physician-administered drugs in a physician office setting.

1. Average sales price (ASP) plus 6 percent, for drugs appearing on the Medicare file.

2. Reimbursement rates for drugs that do not appear on the Medicare file shall be determined utilizing the following alternative methods:

a. the wholesale acquisition cost (WAC) of the drug, if available;

b. if there is no WAC available, the reimbursement rate will be 100 percent of the provider's current invoice for the dosage administered.

J. Clotting Factor. Pharmacy claims for clotting factor will be reimbursed using the brand/generic drug reimbursement methodology.

K. Investigational or Experimental Drugs. Investigational or experimental drugs shall not be reimbursed by Medicaid.

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 32:1065 (June 2006), amended LR 34:88 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1561 (July 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1185 (June 2017), LR 43:1554 (August

2017), LR 44:1020 (June 2018), LR 45:

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 and 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 and no direct or indirect cost to the provider to provide the same level of service. These

provisions will have no impact the provider's ability to provide the same level of service as described in HCR 170.

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. The deadline for submitting written comments is at close of business, 4:30 p.m., on April 1, 2019.

Interested persons may submit a written request to conduct a public hearing either by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629, fax to (225) 342-5568, or email to LDHRulemaking@la.gov; however, such request must be received no later than 4:30 p.m. on March 12, 2019. 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 March 28, 2019 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 Stanley Bordelon at (225) 219-3454 after March 12, 2019. 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.

Rebekah E. Gee MD, MPH

Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Veronica Dent
Phone: 342-3238
Dept.: Health
Office: Bureau of Health Services Financing

Return Address: P.O. Box 91030
Baton Rouge, LA

Rule Title: Pharmacy Benefits Management Program
Federal Upper Payment Limits and Physician-Administered Drugs Reimbursement

Date Rule Takes Effect: May 20, 2019

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 implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 18-19. It is anticipated that $1,188 ($594 SGF and $594 FED) will be expended in FY 18-19 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 18-19. It is anticipated that $594 will be collected in FY 18-19 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 NON-GOVERNMENTAL GROUPS (Summary)

This proposed rule provides technical amendments to the provisions governing reimbursement in the Pharmacy Benefits Management Program in order to: 1) reinstate the federal upper payment limits provisions that were erroneously repealed in the Notice of Intent published in the January 20, 2019 edition of the Louisiana Register; 2) align the reimbursement provisions in the administrative Rule for physician-administered drugs in a physician office setting with the language in the corresponding Medicaid State Plan Amendment approved by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS); and 3) ensure that these provisions are appropriately promulgated in the Louisiana Administrative Code. It is anticipated that implementation of this proposed rule will not result in programmatic costs to the pharmacy program in FY 18-19, FY 19-20 and FY 20-21, but will be beneficial by providing accurate and clearly-defined reimbursement requirements for federal upper payment limits and physician-administered drugs in a physician office setting, in compliance with CMS requirements.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Signature of Agency Head or Designee	Evan Brasseaux, Staff Director Legislative Fiscal Officer or Designee
Jen Steele, Medicaid Director Typed name and Title of Agency Head or Designee	2/8/19 Date of Signature
Bhakhar Todd LDH/BHSF Budget Head	02/07/19 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 reimbursement in the Pharmacy Benefits Management Program in order to: 1) reinstate the federal upper payment limits provisions that were erroneously repealed in the Notice of Intent published in the January 20, 2019 edition of the Louisiana Register; 2) align the reimbursement provisions in the administrative Rule for physician-administered drugs in a physician office setting with the language in the corresponding Medicaid State Plan Amendment approved by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS); and 3) ensure that these provisions are appropriately promulgated in the Louisiana Administrative Code.

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 amended the provisions governing the Pharmacy Benefits Management Program in order to revise the reimbursement methodology for physician-administered drugs in a physician office setting to bring the rates current and to incorporate a mechanism for periodic updates to the rates in compliance with U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) requirements (Louisiana Register, Volume 44, Number 6). The department promulgated a Notice of Intent which proposed to amend the provisions governing pharmacy ingredient cost reimbursement in order to change the reimbursement methodology from average acquisition cost to the national average drug acquisition cost (Louisiana Register, Volume 45, Number 1). The department subsequently determined that the Notice of Intent published in the January 20, 2019 edition of the Louisiana Register erroneously repealed the provisions governing federal upper payment limits.

The department now proposes to amend the provisions governing reimbursement in the Pharmacy Benefits Management Program in order to: 1) reinstate the federal upper payment limits provisions; 2) align the reimbursement methodology for physician-administered drugs in a physician office setting with the corresponding CMS-approved State Plan Amendment; and 3) ensure that these provisions are appropriately promulgated in the Louisiana Administrative Code.

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 18-19. In FY 18-19, $1,188 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 18-19	FY 19-20	FY 20-21
PERSONAL SERVICES			
OPERATING EXPENSES	$1,188	$0	$0
PROFESSIONAL SERVICES			
OTHER CHARGES			
REPAIR & CONSTR.			
POSITIONS (#)			
TOTAL	**$1,188**	**$0**	**$0**

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 18-19, $1,188 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 18-19	FY 19-20	FY 20-21
STATE GENERAL FUND	$594	$0	$0
SELF-GENERATED			
FEDERAL FUND	$594	$0	$0
OTHER (Specify)			
Total	**$1,188**	**$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 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.

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 18-19**	**FY 19-20**	**FY 20-21**
STATE GENERAL FUND			
AGENCY SELF-GENERATED			
RESTRICTED FUNDS*			
FEDERAL FUNDS	$594	$0	$0
LOCAL FUNDS			
Total	**$594**	**$0**	**$0**

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.

In FY 18-19, $594 will be collected for the federal share of the administrative 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 provides technical amendments to the provisions governing reimbursement in the Pharmacy Benefits Management Program in order to: 1) reinstate the federal upper payment limits provisions that were erroneously repealed in the Notice of Intent published in the January 20, 2019 edition of the Louisiana Register; 2) align the reimbursement provisions in the administrative Rule for physician-administered drugs in a physician office setting with the language in the corresponding Medicaid State Plan Amendment approved by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS); and 3) ensure that these provisions are appropriately promulgated in the Louisiana Administrative Code.

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

It is anticipated that implementation of this proposed rule will have no programmatic costs to the pharmacy program in FY 18-19, FY 19-20 and FY 20-21, but will be beneficial by providing accurate and clearly-defined reimbursement requirements for federal upper payment limits and physician-administered drugs in a physician office setting, in compliance with CMS requirements.

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.