NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Pharmacy Benefits Management Program
Pharmacy Ingredient Cost Reimbursement
(LAC 50:XXIX.105 and Chapter 9)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.105 and Chapter 9 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 proposes to amend the provisions governing reimbursement in the Pharmacy Benefits Management Program in order to change the pharmacy ingredient cost reimbursement methodology from average acquisition cost to the national average drug acquisition cost.

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. 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 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 A. General Provisions

§901. Definitions

Average Acquisition Cost (AAC)—Repealed.

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National Average Drug Acquisition Cost (NADAC)—a national pricing benchmark that is reflective of actual invoice costs that pharmacies pay to acquire prescription and over-the-counter drugs. It is based upon invoice cost data collected from retail community pharmacies and reflects actual drug purchases.

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Usual and Customary Charge—the lowest price the pharmacy would charge to a particular customer if such customer were paying cash for the identical prescription drug or prescription drug services on the date dispensed.

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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 32:1061 (June 2006), amended LR 34:87 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1558 (July 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017), LR 43:1554 (August 2017), LR 45:

Subchapter C. Estimated Acquisition Cost

§935. Estimated Acquisition Cost Formula

A. Estimated acquisition cost (EAC) is the national average drug acquisition cost (NADAC) of the drug dispensed. If there is

not a NADAC available, the EAC is equal to the wholesale acquisition cost, as reported in the drug pricing compendia utilized by the department's fiscal intermediary/pharmacy benefits manager (PBM).

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 32:1064 (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 43:1184 (June 2017), LR 45:

Subchapter D. Maximum Allowable Costs

§945. Reimbursement Methodology

A. - A.1. ...

B. Payment will be made for medications in accordance with the payment procedures for any fee-for-service (FFS) Medicaid eligible person.

C. - F. ...

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 32:1064 (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 43:1184 (June 2017), LR 45:

§949. Fee for Service Cost Limits

A. Brand Drugs. The department shall make payments for single source drugs (brand drugs) based on the lower of:

1. national average drug acquisition cost (NADAC) plus the professional dispensing fee:

a. if no NADAC is available, use the wholesale acquisition cost (WAC) plus the professional dispensing fee; or

2. - 2.a. ...

B. Generic Drugs. The department shall make payments for multiple source drugs (generic drugs), other than drugs subject to "physician certifications", based on the lower of:

1. NADAC plus the professional dispensing fee:

a. if no NADAC is available, use the WAC plus the professional dispensing fee; or

2. 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.

3. - 3.a. Repealed.

C. 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.

a. - b. Repealed.

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; and

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

3. - 3.c. Repealed.

D. 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 are not permitted to bill 340B stock to Medicaid. Fee-for-service outpatient hospital claims for 340B drugs shall use a cost to charge methodology on the interim and settled at cost during final 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.

1. - 2.c. Repealed.

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

F. 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.

G. 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.

H. 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. Reimbursement for Medicaid-covered physician-administered drugs in a physician office setting shall be established at the current Louisiana Medicare rate, which is average sales price (ASP) plus 6 percent, for drugs appearing on the Medicare file.

2. Reimbursement rates for physician-administered drugs in a physician office setting 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 the drug has no WAC available, one of the following methods shall be used:

i. the provider's actual cost of the drug as documented by invoice or other acceptable documentation as deemed appropriate by the department;

ii. Medicaid rate of other states;

iii. commercial payer rate; or

iv. medical consultant recommendation.

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

1. - 2.b.iv. Repealed.

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

K. Repealed.

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:

Subchapter E. 340B Program

§961. Definitions

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Estimated Acquisition Cost (EAC)—the national average drug acquisition cost (NADAC) of the drug dispensed. If there is not a NADAC available, the EAC is equal to the wholesale acquisition cost, as reported in the drug pricing compendia utilized by the department's fiscal intermediary.

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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 32:1066 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1186 (June 2017), LR 43:1555 (August 2017), 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, but may reduce the total direct and 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 this proposed Rule increases payments to providers for the same services they already render.

Interested persons may submit written comments about the proposed Rule 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 March 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 February 9, 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 February 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 February 9, 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 Pharmacy Ingredient Cost Reimbursement

Date Rule Takes Effect: April 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 result in estimated state general fund net programmatic costs of approximately $88,521 for FY 18-19 due to the May 2019 implementation of the provisions, $1,109,380 for FY 19-20 and $1,132,016 for FY 20-21. The required state general fund match will be offset by the anticipated revenue collections from the Medicaid Assistance Trust Fund premium taxes in the amount of approximately $21,500 in FY 18-19, $270,000 in FY 19-20, $270,000 in FY 20-21. It is anticipated that $1,296 ($648 SGF and $648 FED) will be expended in FY 18-19 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 64.67 percent in FY 18-19 and 65.79 percent in FY 19-20 and FY 20-21 for the projected non-expansion population, and an FMAP rate of 93.5 percent in FY 18-19, 91.5 percent in FY 19-20 and 90.0 percent in FY 20-21 for the projected expansion population.

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 $258,858 for FY 18-19, $3,267,620 for FY 19-20 and $3,244,984 for FY 20-21. The proposed rule will also increase revenue collections by approximately $21,500 in FY 18-19, $270,000 in FY 19-20, $270,000 in FY 20-21 from the Medicaid Assistance Trust Fund premium taxes. It is anticipated that $648 will be expended in FY 18-19 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 64.67 percent in FY 18-19 and 65.79 percent in FY 19-20 and FY 20-21 for the projected non-expansion population, and an FMAP rate of 93.5 percent in FY 18-19, 91.5 percent in FY 19-20 and 90.0 percent in FY 20-21 for the projected expansion population.

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

This proposed rule amends the provisions governing reimbursement in the Pharmacy Benefits Management Program in order to change the pharmacy ingredient cost reimbursement methodology from average acquisition cost to the national average drug acquisition cost (NADAC). The proposed rule will increase payments to pharmacy providers. It is anticipated that implementation of this proposed rule will result in an increase in programmatic expenditures in the pharmacy program by approximately $346,083 for FY 18-19, $4,377,000 for FY 19-20 and $4,377,000 for FY 20-21 which will be paid for by an increase in drug rebate revenues from the implementation of a single preferred drug list for fee-for-service and managed care that allows the state to capture supplemental rebates on MCO pharmacy claims.

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
Jen Steele, Medicaid Director Typed name and Title of Agency Head or Designee	1/10/19 Date of Signature
Bhaskar Jacob LDH/BHSF Budget Head	01/10/19 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 change the pharmacy ingredient cost reimbursement methodology from average acquisition cost to the national average drug acquisition cost.

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 proposes to amend the provisions governing reimbursement in the Pharmacy Benefits Management Program in order to change the pharmacy ingredient cost reimbursement methodology from average acquisition cost to the national average drug acquisition cost.

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, this proposed rule will result in a net increase of programmatic costs of approximately $347,379 for FY 18-19, $4,377,000 for FY 19-20 and $4,377,000 for FY 20-21. In FY 18-19, $1,296 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) __X__ If no, provide justification as to why this rule change should be published at this time.

Act 2 of the 2018 Second Extraordinary 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.

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	$1,296	$0	$0
PROFESSIONAL SERVICES			
OTHER CHARGES	$346,083	$4,377,000	$4,377,000
REPAIR & CONSTR.			
POSITIONS (#)			
TOTAL	**$347,379**	**$4,377,000**	**$4,377,000**

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 18-19, $1,296 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 18-19	FY 19-20	FY 20-21
STATE GENERAL FUND	$67,021	$839,380	$862,016
SELF-GENERATED			
FEDERAL FUND	$258,858	$3,267,620	$3,244,984
OTHER (Specify) ***Medicaid Assistance Trust Fund Premium Taxes used to offset the State General Fund***	$21,500	$270,000	$270,000
Total	**$347,379**	**$4,377,000**	**$4,377,000**

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, additional revenue will be generated in pharmacy rebates due to the implementation of a single statewide Preferred Drug List. These funds will be used to support this rule change.

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* ***Medicaid Assistance Trust Fund Premium Taxes used to offset the State General Fund***	$21,500	$270,000	$270,000
FEDERAL FUNDS	$258,858	$3,267,620	$3,244,984
LOCAL FUNDS			
Total	**$280,358**	**$3,537,620**	**$3,514,984**

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 increase in the federal share of programmatic expenditures for the Medicaid program. In FY 18-19, $648 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 reimbursement in the Pharmacy Benefits Management Program in order to change the pharmacy ingredient cost reimbursement methodology from average acquisition cost to the national average drug acquisition cost (NADAC).

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

The proposed rule will increase payments to pharmacy providers. It is anticipated that implementation of this proposed rule will result in an increase in programmatic expenditures in the pharmacy program by approximately $346,083 for FY 18-19, $4,377,000 for FY 19-20 and $4,377,000 for FY 20-21 which will be paid for by an increase in drug rebate revenues from the implementation of a single preferred drug list for fee-for-service and managed care that allows the state to capture supplemental rebates on MCO pharmacy claims.

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.