NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Pharmacy Benefits Management Program
Provider Participation and Reimbursement
(LAC 50:XXIX.Chapters 1 and 9)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.Chapters 1 and 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 provides coverage and reimbursement for prescription drugs to Medicaid eligible recipients enrolled in the Medicaid Program. The department promulgated a Notice of Intent to amend the provisions governing the Pharmacy Benefits Management Program in order to clarify requirements regarding 340B-covered entities, and to revise the reimbursement methodology to include federal upper limits (FUL), new copayment exemptions and over-the-counter medications added for expansion benefits pursuant to CMS recently released regulations (*Louisiana Register*, Volume 43, Number 1).

The department now proposes to amend the provisions governing the Pharmacy Benefits Management Program in order to

clarify the provisions of the January 20, 2017 Notice of Intent and to: 1) revise the definitions for usual and customary charge and general public; 2) clarify billing/reimbursement requirements for 340B entities that are carved-out of Medicaid; 3) revise the reimbursement language for Federal Supply Schedule and Nominal Price; 4) revise the definition for contract pharmacy; and 5) clarify professional dispensing fee provisions.

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. - G. ...

H. Point-of-Sale Prospective Drug Utilization Review System. This on-line point-of-sale system provides electronic claims management to evaluate and improve drug utilization quality. Information about the patient and the drug will be analyzed through the use of therapeutic modules in accordance with the standards of the National Council of Prescription Drug Programs. The purpose of prospective drug utilization review is to reduce duplication of drug therapy, prevent drug-to-drug interactions, and assure appropriate drug use, dosage and duration. The prospective modules may screen for drug

interactions, therapeutic duplication, improper duration of therapy, incorrect dosages, clinical abuse/misuse and age restrictions. Electronic claims submission inform pharmacists of potential drug-related problems and pharmacists document their responses by using interventions codes. By using these codes, pharmacists will document prescription reporting and outcomes of therapy for Medicaid recipients.

I. - I.5. ...

6. Prescribers and pharmacy providers are required to participate in the educational and intervention features of the Pharmacy Benefits Management System.

J. - L. ...

AUTHORITY NOTE: Promulgated in accordance with R.S, 46:153, 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:

§109. Medicare Part B

A. The Department of Health, Bureau of Health Services Financing pays the full co-insurance and the Medicare deductible on outpatient pharmacy claims for services reimbursed by the

Medicaid Program for Medicaid recipients covered by Medicare Part B.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 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 32:1055 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

§111. Copayment

A. - A.2.d ...

B. The following population groups are exempt from copayment requirements:

1. - 4. ...

4. Native Americans and Alaskan Eskimos;

5. ...

6. home and community-based services waiver recipients.

C. - C.4. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 32:1055 (June 2006),

amended by the Department of Health, Bureau of Health Services Financing, LR 43:

Chapter 9. Methods of Payment

Subchapter A. General Provisions

§901. Definitions

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Usual and Customary Charge- the price the provider most frequently charges the general public for the same drug.

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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:

Subchapter B. Professional Dispensing Fee

§915. General Provisions

A. The professional dispensing fee shall be set by the department and reviewed periodically for reasonableness, and when deemed appropriate by the Medicaid Program, may be adjusted considering such factors as fee studies or surveys.

Adjustment Factors—Repealed.

Base Rate—Repealed.

Base Rate Components—Repealed.

Maximum Allowable Overhead Cost—Repealed.

Overhead Year—Repealed.

B. Provider participation in the Louisiana Cost of Dispensing Survey shall be mandatory. A provider's failure to cooperate in the survey shall result in his/her removal from participation as a provider of pharmacy services in the Medicaid Program. Any provider removed from participation shall not be allowed to re-enroll until a professional dispensing fee survey document is properly completed and submitted to the department.

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 36:1558 (July 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

§917. Maximum Allowable Overhead Cost Calculation

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, Bureau of Health Services Financing, LR 36:1559

(July 2010), repealed by the Department of Health, Bureau of Health Services Financing, LR 43:

§919. Parameters and Limitations

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, Bureau of Health Services Financing, LR 36:1560 (July 2010), repealed by the Department of Health, Bureau of Health Services Financing, LR 43:

§921. Interim Adjustment to Overhead Cost

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, Bureau of Health Services Financing, LR 36:1560 (July 2010), repealed by the Department of Health, Bureau of Health Services Financing, LR 43:

§923. Cost Survey

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, Bureau of Health Services Financing, LR 36:1560

(July 2010), repealed by the Department of Health, Bureau of Health Services Financing, LR 43:

§925. Dispensing Fee

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 32:1064 (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), repealed by the Department of Health, Bureau of Health Services Financing, LR 43:

Subchapter D. Maximum Allowable Costs

§949. Fee for Service Cost Limits

A. - A.2. ...

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.

i. - iii. Repealed.

B. - B.3. ...

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.

i. - iii. Repealed.

C. - D.2.c. ...

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 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.

F. Fee-For-Service Drugs. Drugs acquired at federal supply schedule (FSS) and at nominal price shall be reimbursed at actual acquisition cost plus a professional dispensing fee.

G. - K. Reserved.

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:

Subchapter E. 340B Program

§961. Definitions

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Contract Pharmacy—a pharmacy under contract with a covered entity that provides services to the covered entity's patients, including the service of dispensing the covered entity's 340B drugs, in accordance with Health Resources and Services Administration (HRSA) guidelines (75 FR 10272, March 5, 2010). Contract pharmacies are not allowed to bill Medicaid for pharmacy claims.

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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:

Subchapter H. Vaccines

§991. Vaccine Administration Fees

A. Effective for dates of service on and after October 10, 2009, the reimbursement to pharmacies for immunization administration (intramuscular or intranasal) performed by qualified pharmacists, is a maximum of $15.22. This fee includes counseling, when performed.

B. 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, Bureau of Health Services Financing, LR 36:1783 (August 2010), amended LR 40:82 (January 2014), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

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, 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.

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, June 29, 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 Statement: Robert Andrepont
Phone: 342-8769

Dept.: Health
Office: Bureau of Health Services Financing

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

Rule Title: Pharmacy Benefits Management Program
Provider Participation and Reimbursement

Date Rule Takes Effect: August 20, 2017

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 16-17. It is anticipated that $1,404 ($702 SGF and $702 FED) will be expended in FY 16-17 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 not affect revenue collections other than the federal share of the promulgation costs for FY 16-17. It is anticipated that $702 will be collected in FY 16-17 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 amends the provisions governing the Pharmacy Benefits Management Program in order to clarify the provisions of the January 20, 2017 Notice of Intent and to: 1) revise the definitions for usual and customary charge and general public; 2) clarify billing/reimbursement requirements for 340B entities that are carved-out of Medicaid; 3) revise the reimbursement language for Federal Supply Schedule and Nominal Price; 4) revise the definition for contract pharmacy; and 5) clarify professional dispensing fee provisions. It is anticipated that implementation of this proposed rule will not have economic costs, but will be beneficial to pharmacy providers in FY 16-17, FY 17-18 and FY 18-19 by providing clear and concise Pharmacy Program provisions.

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

5/10/17
Date of Signature

Bhaskar Todd
LDH/BHSF Budget Head

05/10/17
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 the Pharmacy Benefits Management Program in order to clarify the provisions of the January 20, 2017 Notice of Intent and to: 1) revise the definitions for usual and customary charge and general public; 2) clarify billing/reimbursement requirements for 340B entities that are carved-out of Medicaid; 3) revise the reimbursement language for Federal Supply Schedule and Nominal Price; 4) revise the definition for contract pharmacy; and 5) clarify professional dispensing fee provisions.

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 provides coverage and reimbursement for prescription drugs to Medicaid eligible recipients enrolled in the Medicaid Program. The department promulgated a Notice of Intent to amend the provisions governing the Pharmacy Benefits Management Program in order to clarify requirements regarding 340B-covered entities, and to revise the reimbursement methodology to include federal upper limits (FUL), new copayment exemptions and over-the-counter medications added for expansion benefits pursuant to CMS recently released regulations (Louisiana Register, Volume 43, Number 1).

The department now proposes to amend the provisions governing the Pharmacy Benefits Management Program in order to clarify the provisions of the January 20, 2017 Notice of Intent and to: 1) revise the definitions for usual and customary charge and general public; 2) clarify billing/reimbursement requirements for 340B entities that are carved-out of Medicaid; 3) revise the reimbursement language for Federal Supply Schedule and Nominal Price; 4) revise the definition for contract pharmacy; and 5) clarify professional dispensing fee provisions.

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 16-17. In FY 16-17, $1,404 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 16-17	FY 17-18	FY 18-19
PERSONAL SERVICES			
OPERATING EXPENSES	$1,404	$0	$0
PROFESSIONAL SERVICES			
OTHER CHARGES			
REPAIR & CONSTR.			
POSITIONS (#)			
TOTAL	**$1,404**	**$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 16-17, $1,404 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 16-17	FY 17-18	FY 18-19
STATE GENERAL FUND	$702	$0	$0
SELF-GENERATED			
FEDERAL FUND	$702	$0	$0
OTHER (Specify)			
Total	**$1,404**	**$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 16-17**	**FY 17-18**	**FY 18-19**
STATE GENERAL FUND			
AGENCY SELF-GENERATED			
RESTRICTED FUNDS*			
FEDERAL FUNDS	$702	$0	$0
LOCAL FUNDS			
Total	**$702**	**$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 16-17, $702 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 amends the provisions governing the Pharmacy Benefits Management Program in order to clarify the provisions of the January 20, 2017 Notice of Intent and to: 1) revise the definitions for usual and customary charge and general public; 2) clarify billing/reimbursement requirements for 340B entities that are carved-out of Medicaid; 3) revise the reimbursement language for Federal Supply Schedule and Nominal Price; 4) revise the definition for contract pharmacy; and 5) clarify professional dispensing fee provisions.

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 not have economic costs, but will be beneficial to pharmacy providers in FY 16-17, FY 17-18 and FY 18-19 by providing clear and concise Pharmacy Program provisions.

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.