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 ~~eight~~ 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 ~~in~~ 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. ~~Physicians~~ Prescribers and pharmacy providers ~~will be~~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- ~~a pharmacy's charge to the general public that reflects all advertised savings, discounts, special promotions or other programs, including membership-based discounts initiated to reduce prices for product costs available to the general public a special population or an inclusive category of customers~~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. ~~Maximum Allowable Overhead Cost~~Professional Dispensing Fee

§915. ~~Cost Determination~~General Provisions

A. ~~Definitions~~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—

~~a. CPI-all item factor;~~

~~b. CPI-medical care factor;~~

~~c. Wage Factor. Each of the above adjustment factors is computed by dividing the value of the corresponding index for December of the year preceding the overhead year and by the value of the index one year earlier (December of the second preceding year);~~

~~d. ROI. One year treasury bill rate applied to a portion of prescription drug cost (17 percent) in recognition of inventories maintained for the purpose of filling prescriptions.~~Repealed.

Base Rate—~~the rate calculated in accordance with §917.A.2, plus any base rate adjustments which are in effect at the time of calculation of new rates or adjustments. The base rate was initially calculated using the 1990/91 fee survey~~

~~findings of average cost for pharmacies representative of the average pharmacy participating in Medicaid reimbursement (15,000 - 50,000 Rx volume). This rate was then inflated forward to December 1990 to establish the first overhead cost maximum.~~Repealed.

Base Rate Components—~~the base rate is the summation of the components shown below. Each component is intended to set the maximum allowable for the costs indicated by its name.~~

~~Base Rate Component~~	~~Adjustment Factor~~
~~Pharmacist Salaries~~	~~CPI-Medical Care~~
~~Other Salaries~~	~~WAGE~~
~~Other Routine Services~~	~~CPI-All Items~~
~~Inventory Cost~~	~~ROI(1)~~
~~Fixed Cost~~	~~None(2)~~
~~Return on Equity~~	~~None (3)~~

	~~(1)No return on equity allowed~~
	~~(2)No inflation allowed~~
	~~(3)Adjusted by ROE Factor~~
	~~(4)Indices~~

~~a. CPI-All Items. The Consumer Price Index for all Urban Consumers - Southern Region (all items line of Table 12) as published by the United States Department of Labor.~~

~~b. CPI-Medical Care. The Consumer Price Index for all Urban Consumers - Southern Region (Medical Care line of Table 12) as published by the United States Department of Labor.~~

~~c. Wage. The average annual wage for production or nonsupervisory service workers as furnished by the Dallas Regional Office of the Bureau of Labor Statistics of the U.S. Department of Labor. This figure will be obtained by telephone in May and will be utilized to calculate the adjustment factor based upon the change which has occurred since December of the preceding year.~~

~~d. ROI; Interest Rates-Money and Capital Markets. The average percent per year for one year U.S. Treasury~~

~~bills taken from the Federal Reserve Bulletin report on Money Market Rates (line 17) for the preceding calendar year.~~Repealed.

Maximum Allowable Overhead Cost—~~overhead cost is determined through use of cost survey results adjusted by various indices to assure recognition of costs which must be incurred by efficiently and economically operated providers. The cost determined is referred to as a maximum allowable to reflect application of the "lesser of" methodology for determining total reimbursement.~~Repealed.

Overhead Year—~~the one-year period from July 1 - June 30 of the next calendar year during which a particular rate is in effect. It corresponds to a state fiscal year.~~Repealed.

B. ~~Determination of Limits. Limits on overhead cost are established through the overhead cost survey process which classifies cost in accordance with generally accepted accounting principles and Medicare principles regarding the allowability of cost.~~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

~~A. The most recent cost survey results will be utilized to establish base cost for professional salaries; other salaries; other routine costs; and fixed cost. Claims processing data for claims paid in the current overhead period will be utilized to determine average drug cost. Seventeen percent of this cost will be utilized as base prescription inventory. The base prescription inventory amount shall not be added to the overhead cost maximum allowable. Base prescription inventory is recognized as an allowable investment subject to a return on investment only. Calculation of maximum allowable overhead cost per prescription shall be performed as follows:~~

~~1. NORC = ORC x CPIF:~~

~~a. NORC is the new other routine cost component;~~

~~b. ORC is the current (base) routine cost component;~~

~~c. CPIAI is the CPI - All items Economic Adjustment Factor.~~

~~2. NPS = PS x CPIMC:~~

~~a. NPS is the new pharmacist salaries cost component;~~

~~b. PS is the current (base) pharmacist salaries cost component;~~

~~c. CPIMC is the CPI - Medical Care Economic Adjustment Factor.~~

~~3. NOS = OS x W:~~

~~a. NOS is the new other salaries cost component;~~

~~b. OS is the current (base) salaries cost component;~~

~~c. W is the Wage Economic Adjustment Factor.~~

~~4. NROI = ROI x IR:~~

~~a. NROI is the new return on investment component;~~

~~b. ROI is 17 percent of the current average drug cost;~~

~~c. IR is the Interest Rate - Money and Capital Markets~~

~~5. Rate = (NORC + NPS + NOS + FCC) x ROEF + NROI where:~~

~~a. NORC, NPS, NOS, and NROI are computed by formulae in Paragraphs 1-4 above;~~

~~b. FCC is the fixed cost component which does not include prescription drug inventory;~~

~~c. ROEF is the return on equity factor of 1.05 applied to all cost components except return on investment which is calculated separately.~~

~~B. After formal adoption of the new maximum allowable overhead cost, the components computed above will become the base components used in calculating the next year's overhead maximum allowable, unless they are adjusted as provided in §911 below.~~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

~~A. Method of Calculation. All calculations described herein shall be carried out algebraically.~~

~~B. Rounding in all calculations the base maximum allowable and the base components will be rounded to the nearest~~

~~one cent (two decimal places) and the economic adjustment factors will be rounded to four decimal places.~~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

~~A. If an unanticipated change in conditions occurs which affects the overhead costs of at least 50 percent of the enrolled providers by an average of five percent or more, the maximum allowable overhead cost may be adjusted. Medicaid of Louisiana will determine whether or not the maximum allowable overhead cost limit should be changed when requested to do so by 10 percent of the enrolled pharmacies. The burden of proof as to the extent and cost effect of the unanticipated charge will rest with the entities requesting the change. Medicaid of Louisiana, however, may initiate an adjustment without a request to do so.~~

~~1. Temporary Adjustments. Temporary adjustments do not affect the base cost used to calculate a new maximum allowable overhead cost limit. Temporary adjustments may be made in the rate when changes which will eventually be reflected in the economic indices, such as a change in the minimum wage,~~

~~occur after the end of the period covered by the index, i.e., after the December preceding the limit calculation. Temporary adjustments are effective only until the next overhead cost limit calculation which uses economic adjustment factors based on index values computed after the change causing the adjustment.~~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

~~A. Every three years a cost survey shall be conducted which includes cost data for all enrolled pharmacy providers. Participation shall be mandatory for continued enrollment as a pharmacy provider. Cost data from providers who have less than 12 months of operating data shall not be utilized in determining average overhead cost or grouping providers by prescription volume. Pre-desk reviews shall be performed on all cost surveys to determine an average provider profile based upon total prescription volume. Through statistical analysis, minimum and maximum volume ranges shall be established which represent the majority of providers participating in Medicaid reimbursement.~~

~~Cost surveys of providers whose prescription volumes are above or below the volume range established, shall not be utilized in calculating average overhead cost. Information submitted by participants shall be desk reviewed for accuracy and completeness. Field examination of a representative sample of participants shall be primarily random, but geographic location and type of operation shall be taken into consideration in order to ensure examination of pharmacies in various areas of the state and representative of various types of operations.~~

~~B. Cost Finding Procedures. The basic analytical rationale used for cost finding procedures shall be that of full costing. Under full costing, all costs associated with a particular operation are summed to find the total cost. The objective of cost finding shall be to estimate the cost of dispensing prescriptions through generally accepted accounting principles.~~

~~C. Inflation Adjustment. Where data collected from participating pharmacies represents varying periods of time, cost and price data may be adjusted for the inflation that occurred over the relevant period. The appropriate Consumer Price Index Indicator (Table 12, Southern Region, Urban Consumer) and wage indicator produced by the U.S. Department of Labor Statistics shall be utilized.~~

~~D. In addition to cost finding procedures, a usual and customary survey shall be included in the survey instrument. This instrument shall be used to determine the following:~~

~~1. an average usual and customary charge, or gross margin for each pharmacy;~~

~~2. the computation of the net margin per prescription (gross margin less computed dispensing cost per prescription) in order to approximate the average profit per prescription;~~

~~3. computation of the average percentage of markup per prescription; and~~

~~4. the computation of average usual and customary charges shall include adjustments to allow comparability with upper limits for prescription reimbursement utilized by Medicaid of Louisiana.~~

~~E. Statistical Analysis. Statistical analysis shall be undertaken to estimate the cost to pharmacies of dispensing prescriptions. Such analysis shall include, but not be limited to:~~

~~1. an average dispensing cost for pharmacies;~~

~~2. analysis of the correlations among overhead costs and parameters deemed relevant to pharmacy costs;~~

~~3. the statistical relationship between independent variables and dispensing cost shall be analyzed using the~~

techniques of simple linear and stepwise multiple regression. Independent variables may include annual volume of prescriptions filled, pharmacy location, type of ownership, and number of Medicaid claims paid:

a. before regression analysis is performed, efforts shall be made to insure that the data collected during the surveys was accurate and representative, and that errors made during data entry are corrected. Efforts should include tabulations, cross tabulations, data plotting, and visual data inspection.

F. Survey Results

1. Medicaid of Louisiana shall consider survey results in determining whether the maximum allowable overhead cost should be rebased. Where the overhead cost survey findings demonstrate the current maximum allowable is below average cost or above the eightieth percentile of cost, rebasing shall be required.

2. Medicaid of Louisiana may review the survey data and establish a new cost base utilizing the cost survey findings and any other pertinent factors, including, but not limited to:

a. inflation adjustment;

b. application of return on equity;

c. recognition of inventory investment.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

~~A. Maximum Allowable Overhead Cost~~

~~1. The maximum allowable overhead cost will remain at the level established for state fiscal year 1994-95. This maximum allowable overhead cost will remain in effect until the dispensing survey is completed and an alternate methodology is determined.~~

~~2. No inflation indices or any interim adjustments will be applied to the maximum allowable overhead costs.~~

~~B. Provider participation in the Louisiana Dispensing Fee Survey shall be mandatory. Failure to cooperate in the Louisiana Dispensing Fee Survey by a provider shall result in removal from participation as a provider of pharmacy services under Title XIX. Any provider removed from participation shall not be allowed to re-enroll until a dispensing fee survey document is properly completed and submitted to the bureau.~~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.~~is defined as all other non-Medicaid prescriptions, including:~~

~~i. third-party insurance;~~

~~ii. pharmacy benefit management; or~~

~~iii. cash.~~i. – iii. Repealed.

B. – B.3. ...

a. For purposes of these provisions, the term *general public* ~~is defined as all other non-Medicaid prescriptions, including:~~does not include any person whose prescriptions are paid by third-party payors, including health insurers, governmental entities, and Louisiana Medicaid.

~~i. third-party insurance;~~

~~ii. pharmacy benefit management; or~~

~~iii. cash.~~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. ~~Drugs that 340B covered entities purchase outside of the 340B program shall not be 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 ~~not~~ be reimbursed ~~by Medicaid~~ 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 ~~lacks its own pharmacy whereby the contract pharmacy is authorized to dispense 340B-discounted drugs on behalf of the covered entity~~ provides services to the covered entity's patients, including the service of dispensing the covered entity's 340B drugs, in accordance with ~~1996~~ Health Resources and Services Administration (HRSA) guidelines (~~61~~ 75 FR ~~43549~~10272, ~~August 23, 1996~~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. ~~Effective for dates of service on or after January 1, 2011, the reimbursement for administration of the influenza vaccine for all recipients shall be reimbursed at $15.22 for subcutaneous or intramuscular injection, $10.90 for nasal/oral administration or billed charges, whichever is the lesser amount. This fee includes counseling, when performed.~~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