**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determined that the Notice of Intent published in the January 20, 2019 edition of the *Louisiana Register* erroneously repealed the provisions governing federal upper payment limits.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, ~~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 D. Maximum Allowable Costs**

**§949. Fee for Service Cost Limits**

A. – B.1.a. ...

2. ~~the provider's usual and customary charges to the general public not to exceed the department's "maximum payment allowed."~~federal upper payment limits plus the professional dispensing fee; or

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.~~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. ~~Physician Certifications~~Federal Upper Payment Limits for Multiple Source Drugs

1. ~~Limits on payments~~ 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 ~~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~~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. ~~Any practice which precludes the prescriber's handwritten statement~~ Medicaid shall ~~not be accepted as a valid certification. Such practices include, but are not limited to:~~utilize the maximum acquisition cost established by CMS in determining multiple source drug cost.

~~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.~~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. ~~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.~~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. ~~Federal Supply Schedule~~ Fee for Service 340B Purchased Drugs. ~~Drugs acquired at federal supply schedule (FSS) and at nominal price~~ The department shall ~~be reimbursed~~ 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 ~~a~~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. ~~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~~ Federal Supply Schedule Drugs. Drugs acquired at federal supply schedule (FSS) and at a nominal price shall be reimbursed ~~to IHS providers~~at actual acquisition cost plus a professional dispensing fee.

G. ~~Mail Order, Long-Term Care and Specialty Pharmacy. Drugs dispensed~~ Indian Health Service All-Inclusive Encounter Rate. Pharmacy services provided by ~~mail order, long-term care and/or specialty pharmacies (drugs not distributed by a retail community pharmacy) will~~the Indian Health Service (IHS) shall be included in the encounter rate. No individual pharmacy claims shall be reimbursed ~~using the brand/generic drug reimbursement methodology~~to IHS providers.

H. ~~Physician-Administered Drugs. Medicaid-covered physician-administered drugs shall~~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 ~~according to the Louisiana professional services fee schedule. Reimbursement shall be determined utilizing~~ using the ~~following~~brand/generic drug reimbursement 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.~~1. - 2.b.iv. Repealed.

I. ~~Clotting Factor. Pharmacy claims for clotting factor will~~ Physician-Administered Drugs. Medicaid-covered physician-administered drugs shall be reimbursed ~~using~~according to the ~~brand/generic drug reimbursement methodology~~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. ~~Investigational or Experimental Drugs. Investigational or experimental drugs shall not~~Clotting Factor. Pharmacy claims for clotting factor will be reimbursed ~~by Medicaid~~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