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**
**RULE TITLE: Crisis Receiving Centers Licensing Standards**

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 18-19 as these services are not currently covered by Medicaid. It is anticipated that $2,160 will be expended in FY 18-19 for the state's administrative expense for promulgation of this proposed rule and the final rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 18-19 as these services are not currently covered by Medicaid. It is anticipated that $2,160 will be expended in FY 18-19 for the state's administrative expense for promulgation of this proposed rule and the final rule.

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

This proposed Rule amends the provisions governing the licensing of hospital crisis receiving centers in order to adopt provisions to allow free-standing psychiatric hospitals which do not have dedicated emergency departments (EDs) to designate crisis receiving center-specialty units (CRC-SUs) as EDs for patients in need of psychiatric crisis treatment, if the CRC-SU meets all of the same regulations as a hospital ED. Implementation of this proposed Rule will expand access to care for patients in need of crisis mental health services by allowing them to be assessed at a psychiatric hospital without delay, rather than being treated at a traditional hospital emergency department. It is anticipated that the implementation of this proposed rule will not result in economic costs to crisis receiving centers for FY 18-19, FY 19-20 and FY 20-21, but will be beneficial providing accurate, clearly identified licensing standards for psychiatric hospitals to provide crisis receiving services as a specialty unit/ED.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Cecile Castello
Medicaid Director
1901#056

Evan Brasseaux
Staff Director
Louisiana Fiscal Office

**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.

* * *

*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.

* * *

*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.

* * *

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**

* * *

*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.

* * *

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.

**Family Impact Statement**

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.

**Poverty Impact Statement**

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.

**Provider Impact Statement**

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.

**Public Comments**

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.

**Public Hearing**

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**
**RULE TITLE: Pharmacy Benefits Management Program—Pharmacy Ingredient Cost Reimbursement**

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT 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 NONGOVERNMENTAL 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.

Jen Steele
Medicaid Director
1901#057

Evan Brasseaux
Staff Director
Legislative Fiscal Officer

## NOTICE OF INTENT

### Department of Insurance
### Office of the Commissioner

Regulation 100—Coverage of Prescription Drugs through a Drug Formulary (LAC 37:XIII.Chapter 41)

The Department of Insurance, pursuant to the authority of the Louisiana Insurance Code, R.S. 22:1 et seq., and in accordance with the Administrative Procedure Act, R.S. 49:950 et seq., hereby gives notice of its intent to amend Regulation 100 to provide clarification in regards to the requirement of obtaining approval from the commissioner whenever a health insurance issuer implements a modification affecting drug coverage in accordance with Act No. 316 in the 2012 Regular Session.

**Title 37**
**INSURANCE**
**Part XIII. Regulations**
**Chapter 41. Regulation 100—Coverage of Prescription Drugs through a Drug Formulary**

**§14101. Purpose**

A. ….

B. The purpose of the amendment to Regulation 100 is to provide clarification set forth in R.S. 22:1068(F) and R.S. 22:1074(F) in regards to the requirement of obtaining approval from the commissioner whenever a health insurance issuer modifies health insurance coverage offered in the group and individual markets.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 1068(F) and R.S. 22:1074 (F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 38:1028 (April 2012), amended LR 45:

**§14111. Requirements for the Modification Affecting Drug Coverage**

A. - A5. …

B. A health insurance issuer shall notify the commissioner in writing of a modification affecting drug coverage 120 days prior to the renewal date of the policy form as to those modifications enumerated in R.S. 22:1061(5) and set forth in § 14111.A herein. A health insurance issuer shall provide the notice of modification affecting drug coverage as provided for in R.S. 22:1068(D)(3) and R.S. 22:1074(D)(3) and shall only modify the policy or contract of insurance at the renewal of the policy or contract of insurance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1068(F) and R.S. 22:1074(F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 38:1028 (April 2012), amended LR 45: