

NOTICE OF INTENT

**Department of Health
Bureau of Health Services Financing**

**Pharmacy Benefits Management Program
Dispense as Written Electronic Prescribing
(LAC 50:XXIX.Chapters 1,5,7,9 and 11)**

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.Chapters 1,2,7,9 and 11 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 currently only allows handwritten "brand necessary" notation of the medical necessity of brand drugs by prescribing providers in the Pharmacy Benefits Management Program. The department has determined that electronic prescriptions are safer in preventing prescription drug errors from the misreading of handwriting, eliminate the ability to alter or manipulate the prescription, and speed up the workflow process. The department now proposes to amend the provisions governing the Pharmacy Benefits Management Program in order to allow notation of the medical necessity of brand drugs using electronic prescriptions, to allow the state to pursue outcomes-based agreements with manufacturers, and to align the provisions with the current Medicaid State Plan.

Title 50

PUBLIC HEALTH MEDICAL ASSISTANCE

Part XXIX. Pharmacy

Chapter 1. General Provisions

§107. Prior Authorization

A. - C.3. ...

D. Drugs Excluded from Coverage. As provided by §1927(d)(2) of the Social Security Act, the following drugs are excluded from program coverage:

1. select agents when used for anorexia, weight loss, or weight gain, except Orlistat (Xenical®);
2. select agents when used to promote fertility, except vaginal progesterone when used for high-risk pregnancy to prevent premature births;
3. select agents when used for symptomatic relief of cough and cold, except prescription antihistamine and antihistamine/decongestant combination products;
4. select prescription vitamins and mineral products, except:
 - a. prenatal vitamins;
 - b. fluoride preparations;
 - c. vitamin A injection;
 - d. vitamin B injection;
 - e. vitamin D (prescription only);

- f. vitamin K (prescription only);
- g. vitamin B12 injection;
- h. folic acid (prescription only);
- i. niacin (prescription only);
- j. vitamin B6 injection;
- k. vitamin B1 injection;
- l. multivitamin (prescription only);
- m. magnesium injections;
- n. calcium injection; and
- o. urinary PH modifiers (phosphorus, specifically K Phos Neutral and Phospha Neutral);

5. select nonprescription drugs except OTC antihistamines and antihistamine/decongestant combinations and polyethylene glycol 3350 (Miralax®);

6 - 10. Repealed.

E. Otherwise Restricted Drugs

1. The state will cover agents when used for cosmetic purposes or hair growth only when the state has determined that use to be medically necessary.

2. Select drugs for erectile dysfunction, except when used for the treatment of conditions, or indications approved by the FDA, other than erectile dysfunction.

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 45:665 (May 2019), LR 46:

§111. Copayment

A. - A.1. ...

* * *

2. The pharmacy provider shall collect a copayment from the Medicaid recipient for each drug dispensed and covered by Medicaid. The following pharmacy services are exempt from the copayment requirements:

a. - d. ...

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

- a. individuals under the age of 21;
- b. individuals residing in a long-term care facility;
- c. individuals receiving hospice care;
- d. Native Americans and Alaskan Eskimos;

e. women whose basis for Medicaid eligibility is breast or cervical cancer; and

f. home and community-based services waiver recipients.

B. In accordance with federal regulations, the following provisions apply.

1. The provider may not deny services to any eligible individual on account of the individual's inability to pay the copayment amount. However, this service statement does not apply to an individual who is able to pay, nor does an individual's inability to pay eliminate his or her liability for the copayment.

2. Providers shall not waive the recipient copayment liability.

3. Departmental monitoring and auditing will be conducted to determine provider compliance.

4. Violators of this Section maybe subject to a penalty, including but not limited to, termination from the Medicaid Program.

5. The state will ensure Medicaid premiums and cost sharing incurred by all individuals in the Medicaid household do not exceed an aggregate limit of 5 percent of the family's income applied on a monthly basis.

B.6 - C.4. 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, LR 32:1055 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1181 (June 2017), LR 43:1553 (August 2017), LR 46:

§115. Drug Coverage Limits

A. - 5.c. ...

6. The prescribed drug is an excluded or otherwise restricted drug.

7. ...

8. The prescribed drug is not an immunosuppressant drug prescribed and billed to Medicare for a Title XIX transplant recipient who has Medicare Part B coverage.

9. The prescribed drug is not an immunosuppressant drug covered by Medicare Part B which is prescribed for a nontransplant patient with Medicare Part B coverage and identified in the Title XIX provider manual as subject to special billing procedures.

B. Drug Listing

1. - 2. ...

C. 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 32:1055 (June 2006), LR 32:2083 (November 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1182 (June 2017), LR 46:

§119. Maximum Quantity

A. ...

B. When maintenance drugs are prescribed and dispensed for chronic illnesses they shall be in quantities sufficient to effect economy in dispensing and yet be medically sound. Maintenance type drugs should be prescribed and dispensed in a month's supply after the initial fill.

1. - 10.c. Repealed.

C. ...

D. 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 32:1056 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1182 (June 2017), LR 46:

Chapter 5. Narcotics and Controlled Substances

§501. Schedule II Narcotic Analgesic Prescriptions

A. ...

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, Office of the Secretary, Bureau of Health
Services Financing, LR 32:1058 (June 2006), amended by the
Department of Health, Bureau of Health Services Financing, LR
43:1183 (June 2017), LR 46:

Chapter 7. Parenteral Nutrition Therapy

§701. Introduction

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 32:1058 (June 2006), repealed LR 46:

§703. Medical Necessity

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 32:1058 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1183 (June 2017), repealed LR 46:

§707. Prior Authorization

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 32:1060 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017), repealed LR 46:

§709. Intradialytic Parenteral Nutrition

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 32:1061 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017), repealed LR 46:

§713. Equipment and Supplies

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 32:1061 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017), repealed LR 46:

§715. Reimbursement

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 32:1061 (June 2006), repealed LR 46:

Chapter 9. Methods of Payment

Subchapter D. Maximum Allowable Costs

§949. Fee for Service Cost Limits

A. - C.3.c. ...

D. Physician Certifications

1. Limits on payments for multiple source drugs shall not be applicable when the prescriber certifies that the brand name drug is medically necessary for the care and treatment of a recipient in his own handwriting or via an

electronic prescription. Such certification shall be written directly on the prescription, on a separate sheet which is dated and attached to the prescription, or submitted electronically. A standard phrase such as "brand necessary" indicating the medical necessity of the brand will be acceptable.

2. - 2.c. Repealed.

E. - K. ...

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 45:571 (April 2019), LR 45:665 (May 2019), amended LR 46:

Chapter 11. Value-based Agreement Programs

Subchapter E. 340B Program

§1101. General Provisions

A. ...

B. LDH may enter into an agreement with a pharmaceutical manufacturer for outcomes-based contracts. Participation by a pharmaceutical manufacturer in an outcomes-based agreement with the department is voluntary.

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, Bureau of Health Services Financing, LR 43:966 (May 2017), amended LR 45:909 (July 2019), LR 46:

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.

Small Business Analysis

In compliance with Act 820 of the 2008 Regular Session of the Louisiana Legislature, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule will have no impact on small businesses, as described in R.S. 49:965.2 et seq.

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, 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.

Public Comments

Interested persons may submit written comments to Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. The

deadline for submitting written comments is at 4:30 p.m. on November 29, 2019.

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on November 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 November 27, 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 Allen Enger at (225) 342-1342 after November 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

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person

Preparing

Statement: Veronica Dent

Phone: 342-3238

Dept.: Health

Office: Bureau of Health Services
Financing

Return P.O. Box 91030

Address: Baton Rouge, LA

Rule Title:

Pharmacy Benefits Management
Program
Dispense as Written Electronic
Prescribing

Date Rule Takes Effect:

January 20, 2020

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 19-20. It is anticipated that \$1,512 (\$756 SGF and \$756 FED) will be expended in FY 19-20 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 have no effect on revenue collections other than the federal share of the promulgation costs for FY 19-20. It is anticipated that \$756 will be collected in FY 19-20 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 allow notation of the medical necessity of brand drugs using electronic prescriptions, to allow the state to pursue outcomes-based agreements with manufacturers, and to align the provisions with the current Medicaid State Plan. Recipients and providers will benefit from implementation of this proposed Rule as it has been demonstrated that electronic prescriptions are safer in preventing prescription drug errors from the misreading of handwriting, eliminate the ability to alter or manipulate the prescription, and speed up the workflow process. It is anticipated that implementation of this proposed rule will not result in costs to the Pharmacy Program in FY 19-20, FY 20-21 and FY 21-22.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.



Signature of Agency Head
or Designee

Jen Steele, Medicaid Director

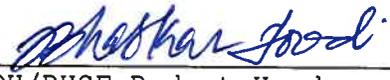
Typed name and Title of
Agency Head or Designee

Evan Brassef, Staff Director

Legislative Fiscal Officer
or Designee

10/10/19

Date of Signature



LDH/BHSF Budget Head

10/10/19

Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberations on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

This proposed rule amends the provisions governing the Pharmacy Benefits Management Program in order to allow notation of the medical necessity of brand drugs using electronic prescriptions, to allow the state to pursue outcomes-based agreements with manufacturers, and to align the provisions with the current Medicaid State Plan.

- 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 currently only allows handwritten "brand necessary" notation of the medical necessity of brand drugs by prescribing providers in the Pharmacy Benefits Management Program. The department has determined that electronic prescriptions are safer in preventing prescription drug errors from the misreading of handwriting, eliminate the ability to alter or manipulate the prescription, and speed up the workflow process. The department now proposes to amend the provisions governing the Pharmacy Benefits Management Program in order to allow notation of the medical necessity of brand drugs using electronic prescriptions, to allow the state to pursue outcomes-based agreements with manufacturers, and to align the provisions with the current Medicaid State Plan.

- 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 the implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 19-20. In FY 19-20, \$1,512 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 19-20	FY 20-21	FY 21-22
PERSONAL SERVICES			
OPERATING EXPENSES	\$1,512	\$0	\$0
PROFESSIONAL SERVICES			
OTHER CHARGES			
REPAIR & CONSTR.			
POSITIONS (#)			
TOTAL	\$1,512	\$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 19-20, \$1,512 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 19-20	FY 20-21	FY 21-22
STATE GENERAL FUND	\$756	\$0	\$0
SELF-GENERATED			
FEDERAL FUND	\$756	\$0	\$0
OTHER (Specify)			
Total	\$1,512	\$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.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

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 19-20	FY 20-21	FY 21-22
STATE GENERAL FUND			
AGENCY SELF-GENERATED			
RESTRICTED FUNDS*			
FEDERAL FUNDS	\$756	\$0	\$0
LOCAL FUNDS			
Total	\$756	\$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 19-20, \$756 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 allow notation of the medical necessity of brand drugs using electronic prescriptions, to allow the state to pursue outcomes-based agreements with manufacturers, and to align the provisions with the current Medicaid State Plan.

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

Recipients and providers will benefit from implementation of this proposed Rule as it has been demonstrated that electronic prescriptions are safer in preventing prescription drug errors from the misreading of handwriting, eliminate the ability to alter or manipulate the prescription, and speed up the workflow process. It is anticipated that implementation of this proposed Rule will not result in costs to the Pharmacy Program in FY 19-20, FY 20-21 and FY 21-22.

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.