

NOTICE OF INTENT

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

**Pharmacy Benefits Management Program
Over-the-Counter At-Home COVID-19 Tests
(LAC 50:XXIX.107)**

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.107 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 U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) requires states to provide reimbursement in the Medical Assistance Program for over-the-counter (OTC) at-home tests for Coronavirus Disease 2019 (COVID-19) that have been authorized by the Food and Drug Administration (FDA). In compliance with CMS requirements, the Department of Health, Bureau of Health Services Financing promulgated an Emergency Rule which amended the provisions governing the Pharmacy Benefits Management Program in order to include coverage for FDA-authorized OTC at-home tests for COVID-19 (*Louisiana Register*, Volume 48, Number 2). This proposed Rule is being promulgated to continue the provisions of the February 4, 2022 Emergency Rule.

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. - 4.o. ...

5. select nonprescription drugs except OTC antihistamines and antihistamine/decongestant combinations and polyethylene glycol 3350 (Miralax®) and OTC at-home COVID-19 FDA-authorized tests;

E. - E.2. ...

AUTHORITY NOTE: Promulgated in accordance with R.S, 36:254, Title XIX of the Social Security Act, and the 1995-96 General Appropriations 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), amended LR 45:665 (May 2019), LR 46:33 (January 2020), LR 48:

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 a positive impact on family functioning, stability and autonomy as described in R.S. 49:972 as it will ensure access to over-the-counter at-home COVID-19 tests.

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 a positive impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973 as it will ensure access to over-the-counter at-home COVID-19 tests.

Small Business Analysis

In compliance with the Small Business Protection Act, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule will

have a positive impact on small businesses, as described in R.S. 49:978.1 et seq. as it will provide reimbursement for a service not previously covered.

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 provides reimbursement for a service not previously covered.

Public Comments

Interested persons may submit written comments to Patrick Gillies, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821. Mr. Gillies is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on April 29, 2022.

Public Hearing

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 April 11, 2022. 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 April 28, 2022 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 April 11, 2022. 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.

Dr. Courtney N. Phillips

Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Veronica Dent Dept.: Health
Phone: 324-3228 Office: Bureau of Health Services Financing
Return Address: P.O. Box 91030 Rule Title: Pharmacy Benefits Management Program
Baton Rouge, LA Over-the-Counter At-Home COVID-19 Tests
Date Rule Takes Effect: February 4, 2022

SUMMARY
(Use complete sentences)

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 STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND 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 result in increased state costs of approximately \$9,456 in SFY 21-22, \$27,559 in SFY 22-23, and \$36,745 in SFY 23-24. It is anticipated that \$540 (\$270 SGF and \$270 FED) will be expended in FY 21-22 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 increase federal revenue collections by approximately \$25,207 for FY 21-22, \$74,811 for FY 22-23, and \$96,971 for FY 23-24. It is anticipated that \$270 will be collected in FY 21-22 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, SMALL BUSINESSES, OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule continues the provisions of the February 4, 2022 Emergency Rule which amends the provisions of the Pharmacy Benefits Management Program in order to include coverage for over-the-counter at-home tests for Coronavirus Disease 2019 (COVID-19) that have been authorized by the Food and Drug Administration, in compliance with requirements of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services. This proposed rule will be beneficial to Medicaid recipients because it will ensure access to over-the-counter at-home COVID-19 tests. Providers will benefit from implementation of this proposed rule since it provides reimbursement for a service that was previously not covered. It is anticipated that implementation of this proposed rule will increase expenditures in the Medicaid program by approximately \$34,123 for FY 21-22, \$102,370 for FY 22-23, and \$133,717 for FY 23-24.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.



Signature of Agency Head or Designee

Patrick Gillies, Medicaid Executive Director
Typed Name & Title of Agency Head or Designee

March 8, 2022
Date of Signature

Evan Brassel, Interim Deputy
Legislative Fiscal Officer or Designee *Fiscal Officer*

3/8/22
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 deliberation 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).

The proposed rule continues the provisions of the February 4, 2022 Emergency Rule which amends the provisions of the Pharmacy Benefits Management Program in order to include coverage for over-the-counter at-home tests for Coronavirus Disease 2019 (COVID-19) that have been authorized by the Food and Drug Administration, in compliance with requirements of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services.

- B. Summarize the circumstances, which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

The U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) requires states to provide reimbursement in the Medical Assistance Program for over-the-counter (OTC) at-home tests for Coronavirus Disease 2019 (COVID-19) that have been authorized by the Food and Drug Administration (FDA). In compliance with CMS requirements, the Department of Health, Bureau of Health Services Financing promulgated an Emergency Rule which amended the provisions governing the Pharmacy Benefits Management Program in order to include coverage for FDA-authorized OTC at-home tests for COVID-19 (*Louisiana Register*, Volume 48, Number 2). This proposed Rule is being promulgated to continue the provisions of the February 4, 2022 Emergency Rule.

- 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.

Yes. It is anticipated that implementation of this proposed rule will result in increased expenditures of approximately \$34,663 for FY 21-22, \$102,370 for FY 22-23, and \$133,717 for FY 23-24. In FY 21-22, \$540 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) _____ Yes. If yes, attach documentation.

(b) X NO. If no, provide justification as to why this rule change should be published at this time

Act 119 of the 2021 Regular Session of the Louisiana Legislature allocated funds to the Medical Vendor Program for payments to providers and the operation of the Medicaid Program, and thereby, authorizes the expenditure of these funds. This proposed rule will benefit recipients by providing coverage for over-the-counter at-home tests for COVID-19.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 22	FY 23	FY 24
Personal Services			
Operating Expenses	\$540	\$0	\$0
Professional Services			
Other Charges	\$34,123	\$102,370	\$133,717
Equipment			
Major Repairs & Constr.			
TOTAL	\$34,663	\$102,370	\$133,717

POSITIONS (#)

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.

The expenses reflected above are the estimated increases in expenditures in the Medicaid program. In FY 21-22, is included 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 22	FY 23	FY 24
State General Fund	\$9,456	\$27,559	\$36,745
Agency Self-Generated			
Dedicated			
Federal Funds	\$25,207	\$74,811	\$121,214
Other (Specify)			
TOTAL	\$34,663	\$102,370	\$133,717

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 THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

The proposed rule has no known impact on local governmental units.

2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

There is no known impact on the sources of local governmental unit funding.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

REVENUE INCREASE/DECREASE	FY 22	FY 23	FY 24
State General Fund			
Agency Self-Generated			
Dedicated Funds*			
Federal Funds	\$25,207	\$74,811	\$96,971
Local Funds			
TOTAL	\$25,207	\$74,811	\$96,971

*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

The amounts reflected above are the estimated increases in the federal share of expenditures in the Medicaid program. In FY 21-22, \$270 will be collected for the federal share of the administrative expense for promulgation of this proposed rule and the final rule.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS

- A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed rule continues the provisions of the February 4, 2022 Emergency Rule which amends the provisions of the Pharmacy Benefits Management Program in order to include coverage for over-the-counter at-home tests for Coronavirus Disease 2019 (COVID-19) that have been authorized by the Food and Drug Administration, in compliance with requirements of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services. This proposed rule will be beneficial to Medicaid recipients because it will ensure access to over-the-counter at-home COVID-19 tests.

- B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

Providers will benefit from implementation of this proposed rule since it provides reimbursement for a service that was previously not covered. It is anticipated that implementation of this proposed rule will increase expenditures in the Medicaid program by approximately \$34,123 for FY 21-22, \$102,370 for FY 22-23, and \$133,717 for FY 23-24.

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.