

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