NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Pharmacy Benefits Management Program
Drug Shortages
(LAC 50:XXIX.105)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.105 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) recommended that the Department of Health, Bureau of Health Services Financing clarify language in the Medicaid State Plan relating to drug shortages of prescribed drugs under the Medical Assistance Program. The department proposes to amend the provisions governing the Pharmacy Benefits Management Program in order to align the language in the *Louisiana Administrative Code* with the required changes requested by CMS to the State Plan relative to shortages of drugs not on the covered drug list, including drugs authorized for import by the Food and Drug Administration (FDA) that may be covered when deemed medically necessary during drug shortages identified by the FDA.

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. - C. ...

D. Drug Shortages. Drugs that are not on the list of covered drugs, including drugs authorized for import by the Food and Drug Administration (FDA), may be covered when deemed medically necessary during drug shortages identified by the FDA.

E. 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, 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.

F. Claims Management. The claims management component is performed through the processing of pharmacy claims against established edits. Claim edit patterns and operational reports are analyzed to review the effectiveness of established edits and to identify those areas where the development of additional edits are needed.

1. - 3. Repealed.

G. Pharmacy Program Integrity. Program integrity is maintained through the following mechanisms:

1. retrospective drug utilization review;

2. Lock-In Program for patient education; and

3. Surveillance and Utilization Review Systems (SURS) Program processes which provide for on-going review for mis-utilization, abuse and fraud and audits of the pharmacy providers.

H. Pharmacy Provider Network. Enrolled Medicaid pharmacy providers are required to comply with all applicable federal and state laws and regulations.

I. Point-of-Sale Prospective Drug Utilization Review System. This on-line point-of-sale system provides electronic claims management to evaluate and improve drug utilization quality. Information about the patient and the drug will be analyzed through the use of therapeutic modules in accordance with the standards of the National Council of Prescription Drug Programs. The purpose of prospective drug utilization review is to reduce duplication of drug therapy, prevent drug-to-drug interactions, and assure appropriate drug use, dosage and duration. The prospective modules may screen for drug interactions, therapeutic duplication, improper duration of therapy, incorrect dosages, clinical abuse/misuse and age restrictions. Electronic claims submission inform pharmacists of potential drug-related problems and pharmacists document their responses by using interventions codes. By using these codes, pharmacists will document prescription reporting and outcomes of therapy for Medicaid recipients.

1. - 5. Repealed.

J. POS/PRO-DUR Requirements Provider Participation.

1. Point-of-sale (POS) enrollment amendment and certification is required prior to billing POS/PRO-DUR system. Annual recertification is required.

2. All Medicaid enrolled pharmacy providers will be required to participate in the Pharmacy Benefits Management System.

3. Eligibility verification is determined at the point of sale.

4. Pharmacy providers and prescribing providers may obtain assistance with clinical questions from the University of Louisiana at Monroe.

5. Prescribers and pharmacy providers are required to participate in the educational and intervention features of the pharmacy benefits management system.

K. Recipient Participation. Pharmacy patients are encouraged to take an active role in the treatment or management of their health conditions through participation in patient counseling efforts with their prescribing providers and pharmacists.

L. Disease and Outcomes Management. Disease management will be focused on improving the drug therapy for certain disease states by developing procedures to assure direct interventions and increasing compliance of patients. Patient populations will be targeted for disease therapy monitoring and educational efforts.

M. Peer Counseling and Conference Management. The department will analyze data for individual prescribers and pharmacists. Quality management strategies will be used for peer counseling and conferences with prescribers and/or pharmacists to assure appropriate prescribing and dispensing.

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 45:570 (April 2019), amended LR 45:665 (May 2019), LR 50:

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 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 no impact on small businesses.

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 Kimberly Sullivan, JD, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030.

Ms. Sullivan is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on August 29, 2024.

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 August 9, 2024. If the criteria set forth in R.S. 49:961(B)(1) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on August 29, 2024 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 August 9, 2024. 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.

Michael Harrington, MBA, MA
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Pharmacy Benefit Management Program—Drug Shortages

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 24-25. It is anticipated that $864 ($432 SGF and $432 FED) will be expended in FY 24-25 for the state's administrative expense for promulgation of this proposed rule and the final rule.

This proposed rule amends the provisions governing the Pharmacy Benefits Management Program in order to align the language in the Louisiana Administrative Code with the required changes requested by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) to the State Plan relative to shortages of drugs not on the covered drug list, including drugs authorized for import by the Food and Drug Administration (FDA) that may be covered when deemed medically necessary during drug shortages identified by the FDA.

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 24-25. It is anticipated that $432 will be collected in FY 24-25 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 NONGOVERNMENTAL GROUPS (Summary)

This proposed rule amends the provisions governing the Pharmacy Benefits Management Program in order to align the language in the Louisiana Administrative Code with the required changes requested by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) to the State Plan relative to shortages of drugs not on the covered drug list, including drugs authorized for import by the Food and Drug Administration (FDA) that may be covered when deemed medically necessary during drug shortages identified by the FDA. Implementation of this proposed rule will not result in costs to providers and small businesses in FY 24-25, FY 25-26, and FY 26-27, and will be beneficial by aligning the administrative rule with the federal regulations governing the Pharmacy Benefits Management Program.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Kimberly Sullivan, JD
Medicaid Executive Director
2407#041

Patrice Thomas
Deputy Fiscal Officer
Legislative Fiscal Office