John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Office of the Secretary

May 5, 2017

M E M O R A N D U M

TO: The Honorable John A. Alario, President, Louisiana Senate
The Honorable Taylor F. Barras, Speaker of the House
The Honorable Fred H. Mills, Jr., Chairman, Senate Committee on Health and Welfare
The Honorable Frank A. Hoffmann, Chairman, House Committee on Health and Welfare
The Honorable Eric LaFleur, Chairman, Senate Finance Committee
The Honorable Cameron Henry, Chairman, House Appropriations Committee

FROM: Rebekah E. Gee MD, MPH
Secretary

RE: Oversight Report on Bureau of Health Services Financing Proposed Rulemaking

In accordance with the Administrative Procedure Act (R.S. 49:950 et seq.) as amended, we are submitting the attached documents for the proposed Rule for Nursing Facilities – Preadmission Screening and Resident Review.

The Department published a Notice of Intent on this proposed Rule in the March 20, 2017 issue of the *Louisiana Register* (Volume 43, Number 3). A public hearing was held on April 27, 2017 at which only Louisiana Department of Health staff were present. No oral testimony was given or written comments received regarding this proposed Rule.

The Department anticipates adopting the Notice of Intent as a final Rule in the June 20, 2017 issue of the *Louisiana Register*.

The following documents are attached:

1. a copy of the Notice of Intent;
2. the public hearing certification; and
3. the public hearing attendance roster.

REG/WJR/YE

Attachments (3)

NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing
and
Office of Aging and Adult Services

Nursing Facilities
Preadmission Screening and Resident Review
(LAC 50:II.Chapter 5)

The Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services propose to amend LAC 50:II.Chapter 5 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The Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services repealed the provisions governing admission reviews, preadmission screening and medical eligibility determination requirements and adopted revised provisions governing nursing facility admissions (*Louisiana Register*, Volume 36, Number 05). The department now proposes to amend the provisions governing admissions for nursing facilities by revising the procedures for the preadmission screening and resident review process in order to: 1) remove the requirement that the level I Preadmission Screening and Resident Review (PASRR) form be completed by a physician; 2) extend the number of days that the level II authority may make an advance group determination for individuals who require convalescent care

in a nursing facility; 3) require nursing facilities to notify the level II authority if a PASRR was not completed or was completed incorrectly; and 4) clarify existing provisions.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE
Part II. Nursing Facilities
Subpart 1. General Provisions

Chapter 5. Admissions

§503. Medical Certification

A. ...

1. The following documents are required for all nursing facility admissions:

a. a Preadmission Screening and Resident Review (level I PASRR) form completed by a qualified health care professional as defined by OAAS. The level I PASRR form addresses the specific identifiers of MI or ID that indicate that a more in-depth evaluation is needed to determine the need for specialized services. The need for this in-depth assessment does not necessarily mean that the individual cannot be admitted to a nursing facility, only that the need for other services must be determined prior to admission; and

b. a level of care eligibility tool (LOCET) assessment.

NOTE: These documents must not be dated more than 30 days prior to the date of admission. The level 1 PASRR form must be signed and dated on the date that it is completed.

2. - 3. ...

B. If the information on the level I PASRR does not indicate that the individual may have a diagnosis of MI and/or ID and he/she meets the criteria for nursing facility level of care, OAAS may approve the individual for admission to the nursing facility.

1. Once approval has been obtained, the individual must be admitted to the facility within 30 days of the date of the approval notice. The nursing facility shall submit a completed BHSF Form 148 to the parish Medicaid office and OAAS indicating the anticipated payment source for the nursing facility services.

C. If the information on the level I PASRR indicates that the individual may have a diagnosis of MI and/or ID, and the individual meets the criteria for nursing facility level of care, the individual shall be referred to the Office of Behavioral Health or the Office for Citizens with Developmental Disabilities (the state's mental health and intellectual disability level II authorities) for a level II screening to determine level of services provided by a nursing facility and whether specialized services are needed.

1. - 2. ...

D. Vendor Payment. Medicaid vendor payment shall not begin prior to the date that medical and financial eligibility is established, and shall only begin once the individual is actually admitted to the facility.

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, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 36:1011 (May 2010), amended by the Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 43:

§505. Categorical Advance Group Determinations

A. In order to assure timely and appropriate care for applicants, the level II authority may make an advance group determination by category that takes into account that certain diagnoses, levels of severity of illness or need for a particular service clearly indicates the need for nursing facility admission or that the provision of specialized services is not normally needed. The applicable level II authority may make an advance group determination that nursing facility care is needed for persons in the following categories.

1. Convalescent Care. If an applicant appears to be in need of level II assessment but is hospitalized for a serious illness and needs time to convalesce before a valid level II assessment can be performed, provisions may be made for temporary medical certification for nursing facility care. The maximum period of time that a level II assessment may be delayed is 100 days. The period of convalescence allowed will be consistent with the diagnosis and medical condition of the individual.

2. - 3.c. ...

d. advanced chronic obstructive pulmonary disease;

3.e. - C. ...

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, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 36:1011 (May 2010), amended by the Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 43:

§509. Changes in Level of Care and Status

A. The nursing facility shall notify the parish Medicaid office via the BHSF Form 148 of the following changes in a resident's circumstances:

1. change in the level of care;

2. transfer to another nursing facility;

3. change in payer source;

4. ...

5. discharge home, death or any other breaks in facility care.

B. The nursing facility must inform the appropriate level II authority if an individual with a diagnosis of MI and/or ID is subject to readmission or interfacility transfer and there has been a substantial change in the individual's condition, or if a level I screen was not completed or was completed incorrectly.

1. - 2. ...

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, Bureau of Health Services Financing and Office of Aging and Adult Services, LR 36:1012 (May 2010), amended by the Department of Health, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 43:

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.

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 or autonomy as described in R.S. 49:972.

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.

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 and no direct or indirect cost to the provider to provide the same level of service. These provisions will have no impact on the provider's ability to provide the same level of service as described in HCR 170.

Interested persons may submit written comments 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. A public hearing on this proposed Rule is scheduled for Thursday, April 27, 2017 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Rebekah E. Gee MD, MPH

Secretary

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

PUBLIC HEARING CERTIFICATION
April 27, 2017
9:30 a.m.

RE: Nursing Facilities
Preadmission Screening and Resident Review
Docket # 04272017-01
Department of Health
State of Louisiana

CERTIFICATION

In accordance with LA R.S. 49:950 et seq., the attached public hearing agenda, together with one digital recording of the public hearing conducted on April 27, 2017 in Baton Rouge, Louisiana constitute the official record of the above-referenced public hearing.

Medicaid Policy and Compliance Section

04/27/17
Date

LDH/BHSF PUBLIC HEARING

Topic - Nursing Facilities – Preadmission Screening and Resident Review

Date – April 27, 2017

PERSONS IN ATTENDANCE

Name	Address	Telephone Number	AGENCY or GROUP you represent
1. Carol Rumfola	628 N 4th St BR 70802	225 342 6943	LDH
2. Ann Burstall			OBH
3. Melanie Richard	628 N. 4th St. BR	(225) 342-4847	OAAS
4.			
5.			
6.			

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Department of Health
Office of the Secretary

May 5, 2017

MEMORANDUM

TO: The Honorable John A. Alario, President, Louisiana Senate
The Honorable Taylor F. Barras, Speaker of the House
The Honorable Fred H. Mills, Jr., Chairman, Senate Committee on Health and Welfare
The Honorable Frank A. Hoffmann, Chairman, House Committee on Health and Welfare
The Honorable Eric LaFleur, Chairman, Senate Finance Committee
The Honorable Cameron Henry, Chairman, House Appropriations Committee

FROM: Rebekah E. Gee MD, MPH
Secretary

RE: Oversight Report on Bureau of Health Services Financing Proposed Rulemaking

In accordance with the Administrative Procedure Act (R.S. 49:950 et seq.) as amended, we are submitting the attached documents for the proposed Rule for Pharmacy Benefits Management Program.

The Department published a Notice of Intent on this proposed Rule in the January 20, 2017 issue of the *Louisiana Register* (Volume 43, Number 1). A public hearing was held on February 27, 2017 at which provider representatives and Louisiana Department of Health staff were present. Oral testimony and written correspondence was received regarding this proposed Rule.

The Department anticipates adopting the Notice of Intent as a final Rule in the June 20, 2017 issue of the Louisiana Register.

The following documents are attached:

1. a copy of the Notice of Intent;
2. the public hearing certification;
3. the public hearing attendance roster;
4. summary of all oral testimony at the public hearing;
5. summary of all written comments received by the agency;
6. the agency's response to comments from Jason Reddish (340B Covered Entities);
7. the agency's response to comments from L. Lee Hamm;

8. the agency's response to comments from Michael Griffin;
9. the agency's response to comments from Paul Salles; and
10. the agency's response to comments from Randal Johnson.

REG/WJR/RKA

Attachments (10)

NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Pharmacy Benefits Management Program
(LAC 50:XXIX.Chapters 1-9)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.Chapters 1-9 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 provides coverage and reimbursement for prescription drugs to Medicaid eligible recipients enrolled in the Medicaid Program. Act 10 of the 2009 Regular Session of the Louisiana Legislature provided that the department may redefine the reimbursement methodology for multiple source drugs in establishing the state maximum allowable cost (MAC) in order to control expenditures to the level of appropriations for the Medicaid Program. In accordance with the provisions of Act 10, the department promulgated an Emergency Rule to redefine the Louisiana maximum allowable cost (LMAC) (*Louisiana Register*, Volume 36, Number 1). In addition, the dispensing fee was increased for drugs with an LMAC.

The department subsequently determined that it was necessary to repeal the January 1, 2010 Emergency Rule in its entirety and amend the provisions governing the methods of payment for prescription drugs to redefine the LMAC (*Louisiana Register*, Volume 36, Number 2). The department promulgated an Emergency Rule to amend the February 1, 2010 Emergency Rule to revise the provisions governing the methods of payment for prescription drugs to further redefine the LMAC and increase the dispensing fee (*Louisiana Register*, Volume 36, Number 3). The department determined that it was necessary to repeal the March 1, 2010 Emergency Rule in its entirety and promulgated an Emergency Rule to amend the provisions governing the methods of payment for prescription drugs to revise the LMAC provisions (*Louisiana Register*, Volume 36, Number 3). The department subsequently promulgated an Emergency Rule to repeal the March 20, 2010 Emergency Rule in its entirety in order to revise the provisions governing the methods of payment for prescription drugs and the dispensing fee (*Louisiana Register,* Volume 38, Number 9).

The department promulgated an Emergency Rule which amended the provisions of the September 5, 2012 Emergency Rule to further revise the provisions governing the methods of payment for prescription drugs and the dispensing fee (*Louisiana Register*, Volume 38, Number 11). Upon further consideration and consultation with the U.S. Department of Health and Human

Services, Centers for Medicare and Medicaid Services (CMS) on the corresponding Medicaid State Plan Amendment, the department determined that it was necessary to rescind the provisions of the November 1, 2012 Emergency Rule governing the reimbursement methodology for services rendered in the Pharmacy Benefits Management Program, and to return to the reimbursement rates in effect on September 5, 2012, along with an increase in the dispensing fee, which is consistent with the currently approved Medicaid State Plan (*Louisiana Register*, Volume 40, Number 10).

The Department now proposes to amend the provisions governing the Pharmacy Benefits Management Program in order to clarify requirements regarding 340B-covered entities, and to revise the reimbursement methodology to include federal upper limits (FUL), new copayment exemptions and over-the-counter medications added for expansion benefits pursuant to CMS recently released regulations.

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. The Louisiana Department of Health reserves the right for ultimate decision making relative to certain drug class

information and drug contraindications or interactions.

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. Average acquisition costs, federal upper payment limits (FUL) and usual and customary charges assist in managing costs on the covered drug list. Federal Upper Limits provide for dispensing of multiple source drugs at established limitations unless the prescribing practitioner specifies that the brand product is medically necessary for a patient. Establishment of co-payments also provides for management.

D. Reimbursement Management. The cost of pharmaceutical care is managed through Average Acquisition Cost (AAC) of the ingredient or through Wholesale Acquisition Cost (WAC) when no AAC is assigned, and compliance with FUL regulations, 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. ...

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

1. - 2. ...

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.

G. ...

H. 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 eight 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 in 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.

I. - I.2. ...

I.3. - I.4. Repealed.

5. Eligibility verification is determined at the

point of sale.

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

7. Prescribers and pharmacy providers will be required to participate in the educational and intervention features of the Pharmacy Benefits Management System.

J. 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.

K. - L. ...

AUTHORITY NOTE: Promulgated in accordance with R.S, 46:153, 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:

§107. Prior Authorization

A. The medication must be prescribed by a practitioner who is authorized to prescribe under state law. The National Drug Code (NDC) must be identified on each pharmacy claim for

reimbursement. Prescription drugs considered for payment are subject to rebates from manufacturers as mandated by federal law and regulations.

B. Covered Drugs. Coverage of drugs shall be limited to specific drug products authorized for reimbursement by therapeutic category and listed by generic name, strength/unit, NDC, and brand name. Those drug products subject to mandatory coverage as a result of a rebate agreement with the federal government will be covered until written notice is received from the Centers for Medicare and Medicaid Services that coverage will be terminated. Providers will be given notice of termination of coverage.

C. Prior Authorization with a Preferred Drug List

1. A prior authorization process is established which utilizes a preferred drug list (PDL) for selected therapeutic classes. Drugs in selected therapeutic classes that are not included on the PDL shall require prescribers to obtain prior authorization. Lists of covered drug products, including those that require prior authorization, will be maintained on the Louisiana Medicaid web site.

2. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within 24 hours of receipt of a prior authorization request. In emergency situations, providers may

dispense at least a 72-hour supply of medication.

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. experimental drugs and investigational drugs;

2. drugs used to treat weight loss, except Orlistat;

3. cough and cold preparations, except some prescription antihistamine/decongestant combination products;

4. cosmetic drugs, except Isotretinoin;

5. - 8. ...

9. vaccines covered in other programs, except influenza vaccine; and

10. ...

E. DESI Drugs. Those drugs that are subject to a Notice of Opportunity for Hearing, as prescribed by Section 1927(k)(2)(A) of the Social Security Act for which the Food and Drug Administration has proposed to withdraw from the market.

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 32:1054 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

§109. Medicare Part B

A. The Department of Health, Bureau of Health Services Financing pays the full co-insurance and the Medicare deductible on pharmacy claims for services reimbursed by the Medicaid Program for Medicaid recipients covered by Medicare Part B.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 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), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

§111. Copayment

A. Payment Schedule

1. ...

***

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

a. services furnished to pregnant women;

b. emergency services;

c. family planning services; and

d. preventive medications as designated by the U.S. Preventive Services Task Force's A and B recommendations;

e. Repealed.

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

1. individuals under the age of 21;

2. individuals residing in a long-term care facility;

3. individuals receiving hospice care;

4. Native Americans;

5. Women whose basis for Medicaid eligibility is breast or cervical cancer; and

6. waiver recipients.

C. 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 §111 will be subject to a penalty such as suspension from the Medicaid Program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 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:

§113. Prescription Limit

A. - B.3. ...

C. The four prescriptions per month limit can be exceeded when the prescriber determines an additional prescription is medically necessary and communicates the following information to the pharmacist in his own handwriting or by telephone or other telecommunications device:

1. ...

2. a valid diagnosis code that is directly related to each drug prescribed that is over the four prescription limit (literal descriptions are not acceptable).

D. - E. ...

F. An acceptable statement and ICD-10-CM, or its successor, diagnosis code are required for each prescription in excess of four per calendar month.

G. ...

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 Human Resources, Office of Family Security, LR 14:88 (February 1988), amended by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 16: 313 (April 1990), LR 29:2115 (October 2003). Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1055 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 35:1901 (September 2009), LR 37:3270 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

§115. Drug Coverage Limits

A. Reimbursement for multi-source prescription drugs shall be limited in accordance with state and federal law and rules pertaining thereto, with the following exception: Reimbursement shall be provided for any drug prescribed by a prescribing provider that, in his professional judgment and within the lawful scope of his practice, he considers appropriate for the diagnosis and treatment of the patient with the following limitations.

1. - 3 ...

4. The prescribed drug is not methadone prescribed only for narcotic addiction.

5. - 5.c. ...

6. The prescribed drug is not a cosmetic drug,

anorexic, cough and cold preparation, or selected nonprescription drug.

7. The prescribed drug is not an experimental or investigational drug which are generally labeled: Caution - limited by federal law to investigational use, unless a specific exception has been granted by the federal government.

8. The prescribed drug is not an immunosuppresant drug prescribed and billed to Medicare within one year from the date of the transplant for a Title XIX 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. Payment shall be made only when billing requirements are met. Requirements may include provision of a physician statement (or copy) verifying the diagnosis attached to each claim submitted.

B. Drug Listing

1. The bureau's fiscal intermediary or agent will provide coverage information on any specific drug. Providers should contact the fiscal intermediary's or agent's provider/pharmacy relations unit when a specific coverage question arises.

2. The Title XIX provider manual shall include a listing of examples of prescribed medications and/or supplies which are not payable under pharmaceutical services of the Medicaid Program.

C. Erectile Dysfunction Drugs. Prescription drugs for the treatment of sexual or erectile dysfunction shall not be covered or reimbursed under the Medicaid Program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 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:

§117. Time Limits

A. Filling Prescriptions. Prescriptions for drugs covered by Medicaid other than a controlled substance shall expire one year after the date prescribed by a licensed prescriber. These prescriptions shall not be refilled more than 11 times in one year. A prescription for a controlled dangerous substance listed in Schedule II shall expire 90 days after the date written, and no refills are allowed. A prescription for a controlled dangerous substance listed in Schedule III, IV or V shall expire six months after the date written. Expired prescriptions shall not be

refillable or renewable. Payment shall be made for prescriptions refilled for controlled substances in Schedule III, IV and V not more than five times or more than six months after issue date and only to the extent indicated by the prescriber on the original prescription, and is restricted by state and federal statutes.

B. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 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 and Hospitals, Bureau of Health Services Financing, LR 38:368 (February 2012), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

§119. Maximum Quantity

A. - C. ...

D. Payment will not be made for narcotics other than opioid agonists/antagonists prescribed only for narcotic addiction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 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:

Chapter 3. Lock-In Program

§303. Recipient Placement in the Lock-In Mechanism

A. Potential lock-in recipients will be identified through review of various reports or by referral from other interested parties. Department of Health designee(s) who are medical professionals examine data for a consistent pattern of misuse/overuse of program benefits by a recipient. Contact with involved providers may be initiated for additional information. The medical professionals render a recommendation to place a recipient in the Physician/Pharmacy Lock-In Program or Pharmacy-Only Lock-In Program. The decision making authority rests solely with the Department of Health, Bureau of Health Services Financing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 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 32:1057 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:3268 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

§307. Notification Directives

A. - A.4. ...

B. The department's contract designee shall be responsible for the following:

1. initiate contact with the recipient in instances when the recipient fails to contact the department, or its contractor;

2. conduct a telephone interview when warranted with the recipient regarding the Lock-In Program and the recipient's rights and responsibilities;

3. ...

4. notify Lock-In providers of their selection.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 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 32:1057 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:3268 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

§309. Restrictions

A. Recipients shall be prohibited from choosing physicians and pharmacists who overprescribe or oversupply drugs. When the agency cannot approve a recipient's choice of provider(s), the Lock-In recipient shall be required to make another selection.

A.1. - B. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 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 32:1057 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:3269 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

§311. Appeals

A. Administration Reconsideration. A recipient may request an administrative reconsideration of the department's determination to place the recipient in the Lock-In Program. An administrative reconsideration is an informal telephone discussion among the Bureau of Health Services Financing staff, the LDH contract designee, and the recipient. An explanation of the reason for recommending the recipient to be placed in the Lock-In Program will be provided to the recipient. An administrative reconsideration is not in lieu of the administrative appeals process and does not extend the time limits for filing an administrative appeal under the provisions of the Administrative Procedure Act. The designated official shall have the authority to affirm the decision, to revoke the decision, to affirm part or revoke in part, or to request additional information from either the department or the

recipient.

B. Administrative Appeal Process. Upon notification of LDH's determination to place the Medicaid recipient into the Lock-In Program, the recipient shall have the right to appeal such action by submitting a written request to the Division of Administrative Law within 30 days of said notification. If an appeal is timely made, the decision to Lock-In is stayed pending the hearing of the appeal.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 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 32:1057 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:3269 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

§313. Changing Lock-In Providers

A. Recipients may change lock-in providers every year without cause. With good cause, they may change lock-in providers only with the bureau's approval. Recipients may change providers for the following "good cause" reasons:

1. - 2. ...

3. the Lock-In provider(s) request(s) that the recipient be transferred; or

4. the Lock-In provider(s) stop(s) participating in the Medicaid Program and does not accept Medicaid as reimbursement for services.

a. The recipient may still receive other program services available through Medicaid such as hospital, transportation, etc., which are not controlled or restricted by placing a recipient in Lock-In for pharmacy and physician services. No recipient on Lock-In status shall be denied the service of a physician or pharmacist on an emergency basis within program regulations. In instances in which a recipient is referred by his Lock-In physician to another enrolled Medicaid physician who is accepting Medicaid recipients, reimbursement shall be made to the physician to whom the recipient was referred.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 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 and Hospitals, Bureau of Health Services Financing, LR 37:3269 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

Chapter 5. Narcotics and Controlled Substances

§501. Schedule II Narcotic Analgesic Prescriptions

A. Schedule II narcotic analgesic prescriptions covered under the Louisiana Medicaid Program shall be filled within 90 days of the date prescribed by a physician or other prescribing practitioner. Also, in accordance with guidance from the drug enforcement agency, the prescriber has the ability to issue multiple prescriptions for the same Schedule II medication to the same patient on the same day. All prescriptions must be dated and signed on the date issued. The prescriber may issue dispensing instruction, e.g., "do not dispense until a specified date."

B. Payment will not be made for narcotics other than opioid agonists/antagonists prescribed only for narcotic addiction.

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:

Chapter 7. Parenteral Nutrition Therapy

§703. Medical Necessity

A. The department's published medical necessity criteria must be met.

B. - J.7. ...

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:

§705. Exclusionary Criteria

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), repealed by the Department of Health, Bureau of Health Services Financing, LR 43:

§707. Prior Authorization

A. Parenteral nutrition therapy may be approved by the Prior Authorization Unit (PAU) at periodic intervals not to exceed six months.

A.1. - B.6. 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:

§709. Intradialytic Parenteral Nutrition

A. Intradialytic Parenteral Nutrition Therapy (IDPN) is parenteral nutrition therapy provided to a recipient with end stage renal disease (ESRD) while the recipient is being dialyzed. IPDN may be approved by the Prior Authorization Unit at periodic intervals not to exceed six months.

B. - 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 32:1061 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

§711. Additional Documentation

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 by the Department of Health, Bureau of Health Services Financing, LR 43:

§713. Equipment and Supplies

A. ...

A.1. - 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 32:1061 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

Chapter 9. Methods of Payment

Subchapter A. General Provisions

§901. Definitions

Average Acquisition Cost (AAC)-the average of net payments that pharmacists made to purchase a drug product, after taking into account such items as purchasing allowances, discounts and rebates as determined through the collection and review of pharmacy invoices and other information deemed necessary by the Medicaid Program, and in accordance with applicable state and federal law.

Average Wholesale Price—Repealed.

***

Professional Dispensing Fee-the fee paid by the Medicaid Program to reimburse for the professional services provided by a pharmacist when dispensing a prescription. Per legislative mandate, the provider fee assessed for each prescription filled in the state of Louisiana, or shipped into the state of

Louisiana, will be reimbursed separately.

Single Source Drug-a drug mandated or sold by one manufacturer or labeler.

Usual and Customary Charge-a pharmacy's charge to the general public that reflects all advertised savings, discounts, special promotions or other programs, including membership-based discounts initiated to reduce prices for product costs available to the general public a special population or an inclusive category of customers.

Wholesale Acquisition Cost (WAC)-the manufacturer's published catalog price for a drug product to wholesalers as reported to Medicaid by one or more national compendia on a weekly basis.

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:

Subchapter C. Estimated Acquisition Cost

§935. Estimated Acquisition Cost Formula

A. *Estimated Acquisition Cost (EAC)* is the average acquisition cost of the drug dispensed. If there is not an AAC 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).

B. - B.4.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 32:1064 (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:

Subchapter D. Maximum Allowable Costs

§945. Reimbursement Methodology

A. Maximum Pharmaceutical Price Schedule

1. The maximum payment by the agency for a prescription shall be no more than the cost of the drug established by the state plus the established professional dispensing fee.

2. Repealed.

B. Payment will be made for medications in accordance with

the payment procedures for any fee-for-service (FFS) Medicaid eligible person. On a periodic basis as ingredient costs change, the department will post a link on its website containing average acquisition cost of drugs.

C. - D. ...

E. Payment will be made to providers only for medications furnished to persons eligible for medical vendor payments on a prescription written by a practitioner who is authorized to prescribe in Louisiana and is enrolled in FFS Medicaid.

F. Payments will be made only for the drugs covered under Louisiana Medicaid's Pharmacy Program.

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:

§947. Payments to Dispensing Physician

A. Payment will be made for medications dispensed by a physician on a continuing basis only when his main office is more than five miles from a facility which dispenses drugs.

1. Under the above circumstances, vendor payments (when the treating prescriber dispenses his own medications and bills Medical Assistance Program under his own name will be made on the same basis as a pharmacist as specified in §945.A.1-2.

B. A prescriber who has a sub-office in an area more than five miles from a pharmacy or other facility dispensing medications will not be paid for medications he dispenses if his main office is within five miles of a pharmacy or other facility dispensing medications.

C. When a prescriber bills Medicaid for medications he dispenses, he shall certify that he himself, or a pharmacist, dispensed the medications and he shall maintain the same records as required of the pharmacist.

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 by the Department of Health, Bureau of Health Services Financing, LR 43:

§949. Cost Limits

A. Brand Drugs. The department shall make payments for single source drugs (brand drugs) based on the lower of:

1. average acquisition cost (AAC):

a. If no AAC is available, use the wholesale

acquisition cost (WAC) plus the professional dispensing fee; or

b. Repealed.

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, *general public* is defined as all other non-Medicaid prescriptions, including:

i. third-party insurance;

ii. pharmacy benefit management; or

iii. cash.

A.3. - A.3.c. Repealed.

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. AAC:

a. If no AAC is available, use the WAC plus the professional dispensing fee;

2. federal upper payment limits plus the professional dispensing fee; or

3. 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, *general*

public is defined as all other non-Medicaid prescriptions, including:

i. third-party insurance;

ii. pharmacy benefit management; or

iii. cash.

C. Federal Upper Payment Limits for Multiple Source Drugs

1. Except for drugs subject to "physician certification", the Medicaid Program shall utilize listings established by the Centers for Medicare and Medicaid Services (CMS) that identify and set upper limits for multiple source drugs that meet the following requirements.

a. All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications).

b. At least three suppliers list the drug, which has been classified by the FDA as category "A" in the aforementioned publication based on listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

2. Medicaid shall utilize the maximum acquisition cost established by CMS in determining multiple source drug cost.

3. The Medicaid Program shall provide pharmacists who

participate in Medicaid reimbursement with updated lists reflecting:

a. the multiple source drugs subject to federal multiple source drug cost requirements;

b. the maximum reimbursement amount per unit; and

c. the date such costs shall become effective.

4. Repealed.

D. 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.

D.2 - D.2.c. ...

E. 340B Purchased Drugs. The department shall make payments for 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. Drugs that 340B covered entities purchase outside of the 340B program shall not be reimbursed by Medicaid. 340B contract

pharmacies are not permitted to bill 340B stock to Medicaid.

E.1. - E.2. Repealed.

F. Fee-For-Service Drugs. Drugs acquired at federal supply schedule (FSS) and at nominal price shall not be reimbursed by Medicaid.

G. 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.

H. 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.

I. Physician Administered Drugs. Physician-administered drugs will be reimbursed based on the applicable fee schedule posted on the Louisiana Medicaid website.

J. Clotting Factor. Pharmacy claims for clotting factor will be reimbursed using the brand/generic drug reimbursement methodology.

K. Investigational or Experimental Drugs. Investigational or experimental drugs shall not be reimbursed by Medicaid.

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:

Subchapter E. 340B Program

§961. Definitions

Actual Acquisition Cost—the covered entity's net payment made to purchase a drug product.

Contract Pharmacy—a pharmacy under contract with a covered entity that lacks its own pharmacy whereby the contract pharmacy is authorized to dispense 340B-discounted drugs on behalf of the covered entity in accordance with 1996 Health Resources and Services Administration (HRSA) guidelines (61 FR 43549, August 23, 1996). Contract pharmacies are not allowed to bill Medicaid for pharmacy claims.

Covered Entity—a provider or program that meets the eligibility criteria for participating in the 340B Program as set forth in Section 340B(a)(4) of the Public Health Service Act. Covered entities include eligible disproportionate share hospitals that are owned by, or under contract with, state or local government, community health centers, migrant health

centers, health centers for public housing, health centers for the homeless, AIDS drug assistance programs and other AIDS clinics and programs, black lung clinics, hemophilia treatment centers, native Hawaiian health centers, urban Indian clinics/638 tribal centers, 340s school-based programs, Title X family planning clinics, sexually-transmitted disease clinics and tuberculosis clinics.

Dispensing Fee—Repealed.

Estimated Acquisition Cost (EAC)-the average acquisition cost of the drug dispensed. If there is not an AAC available, the EAC is equal to the wholesale acquisition cost, as reported in the drug pricing compendia utilized by the department's fiscal intermediary.

***

Professional Dispensing Fee-the fee paid by Medicaid for the professional services provided by a pharmacist when dispensing a prescription. Per legislative mandate, the $.10 provider fee assessed for each prescription filled in the state of Louisiana will be paid separately.

Wholesale Acquisition Cost (WAC)-the manufacturer's published catalog price for a drug product to wholesalers as reported to Medicaid by one or more national compendia on a weekly basis.

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:

§963. Reimbursement

A. Self-administered drugs that are purchased by a covered entity through the 340B program and dispensed to patients who are covered by Medicaid shall be billed to Medicaid at actual acquisition cost (can be no more than the 340B ceiling price) unless the covered entity has implemented the Medicaid carve-out option, in which case 340B drugs should not be billed to Medicaid. All other drugs shall be billed in accordance with existing Louisiana Medicaid reimbursement methodologies. Indian Health Service, tribal and urban Indian pharmacy claims will be reimbursed in the encounter rate.

B. Contract Pharmacies. Contract pharmacies are not allowed to bill 340B drugs to Medicaid; therefore, they should carve out.

C. Professional Dispensing Fees. The covered entity will be reimbursed at the appropriate ingredient cost plus the maximum allowable professional dispensing fee or the usual and customary charge, whichever is less.

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 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:

Subchapter F. Antihemophilia Drugs

§971. Reimbursement

A. Anti-hemophilia drugs purchased by a covered entity through the 340B program and dispensed to Medicaid recipients shall be billed to Medicaid at actual acquisition cost and the professional dispensing fee.

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, amended LR 34:881 (May 2008), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

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.

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.

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.

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.

Interested persons may submit written comments 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. A public hearing on this proposed Rule is scheduled for Monday, February 27, 2017 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Rebekah E Gee MD, MPH

Secretary

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

PUBLIC HEARING CERTIFICATION
February 27, 2017
9:30 a.m.

RE: Pharmacy Benefits
Management Program
Docket # 02272017-04
Department of Health
State of Louisiana

CERTIFICATION

In accordance with LA R.S. 49:950 et seq., the attached public hearing agenda, together with one digital recording of the public hearing conducted on February 27, 2017 in Baton Rouge, Louisiana constitute the official record of the above-referenced public hearing.

Medicaid Policy and Compliance
Section

02/27/17
Date

DHH/BHSF PUBLIC HEARING

Topic – Pharmacy Benefits Management Program

Date – February 27, 2017

Name	Address	Telephone Number	AGENCY or GROUP you represent
7. Sue Fontenot Melvyn Wendt	LDH	342-1367	LDH
8. Tim Sullivan	LDH	342-0207	LDH
9. Kirby Bonvillain		985-381-4899	Teche Action Clinic Pharmacy
10. MARY PATRICIA WRAY	LPCA	225-395-9961	LPCA
11. William Brent, III	1115 Weber Street Franklin, LA 70538	337-828-2550 ext 2146	Teche Action Clinic
12. Theresa Brinkhouse	Zachary, LA		Southeast Health System

DHH/BHSF PUBLIC HEARING

Topic – Pharmacy Benefits Management Program

Date – February 27, 2017

PERSONS IN ATTENDANCE

Name	Address	Telephone Number	AGENCY or GROUP you represent
1. Cornette Scott	State of Louisiana LDH 628 N. 4th Street Baton Rouge LA, 70802	225-342-3881	LDH Medicaid Policy & Compliance
2. Gerrelda Davis	503 Colonial Drive BR, LA 70806	(225) 927-7662	Louisiana Primary Care Association
3. Berry Broussard	TECHE Action Clinic 1115 Weber Street FRANKLIN, LA 70583	(337) 256-4056	TECHE Action Clinic
4. Michael Griffin	Daughters of Charity 3201 Carrollton Ave. New Orleans, LA 70118	(504) 307-1188	Daughters of Charity
5. Julie D. Henderson	"	"	"
6. Theresa Brinkhaus	6351 - Main St Zachary LA 70791 Southeast Community Health	225-306-2000	Southeast Community Health

SUMMARY OF PUBLIC HEARING TESTIMONY

Proposed Rule: Pharmacy Benefits Management Program
Public Hearing Date: February 27, 2017
Docket No. : 02272017-04
Conducted By: Department of Health, Bureau of Health Services Financing Staff

Oral Testimony Given By	Organization Represented	Summary of Comments
Michael G. Griffin	Daughters of Charity Health Centers	1. Concerned that the payment methodology for 340B pharmacies is changing and place them at a disadvantage. Their profits will be reduced and as a charity it will affect services they deliver. Will put them at a disadvantage because they will be competing with traditional pharmacies. 2. Concerned that MCO rebates will not be audited and that 340Bs will not receive the rebates. 3. Their organization will have to reduce or close their pharmacies because they could not afford to operate.
William Brent	Teche Action Clinic	Concerned MCOs will receive savings from reductions of payments to 340Bs of acquisition and dispensing fee.
Mary Patricia Wray	Louisiana Primary Care Association	1. Will force their patients to go elsewhere for drugs. 2. These Rules go beyond the requirements of CMS. 3. Specialty drugs should not be reimbursed on average acquisition cost because costs fluctuate. Believes it should be actual costs. 4. Presents conflict of interest for insurer because it gives advantage to certain people over others. 5. Carve out guidance from CMS does not include 340Bs and applying them would probably be illegal.
Theresa Brinkhaus	Southeast Health Systems	Agrees with previous comments about 340Bs and that 340Bs should get special consideration.
Kirby Bonvillian	Teche Action Clinic	These rules are detrimental to his pharmacy and may have to make some shut down. Will be detrimental to a large patient population.

SUMMARY OF WRITTEN COMMENTS

Proposed Rule: Pharmacy Benefits Management Program
Public Hearing Date: February 27, 2017
Docket No. : 02272017-04
Conducted By: Department of Health, Bureau of Health Services Financing Staff

Written Comments Received From	Mode of Receipt	Summary of Comments
Jason Reddish on behalf of 340B Covered Entities: Morehouse Community Medical Centers; NO/AIDS Task Force d/b/a CrescentCare; Tulane University Health Sciences Center; and Willis-Knighton Health System	Medicaid Policy email account	1. The proposed exclusion of 340B contract pharmacies from Medicaid Managed Care is contrary to law and threatens the fiscal stability of covered entities that lack in-house pharmacies and rely on contract pharmacy arrangements to support their safety net mission. 2. Supplying actual acquisition cost is operationally difficult due to quarterly price changes and the Inability of pharmacies to determine 340B eligibility at the point of sale. 3. BHSF should establish an enhanced 340B program-specific professional dispensing fee. 4. Covered entities should be given more flexibility to carve in and carve out FFS Medicaid and Medicaid MCOs. 5. Most retail pharmacy billing systems identify 340B claims retrospectively, so the state should not require identification of claims at the point of sale.
L. Lee Hamm, MD Tulane University Health Sciences Center	Medicaid Policy email account	1. An averaging methodology does not fulfill CMS' directive and does not approximate AAC. 2. BHSF must establish a separate dispensing fee for specialty pharmacies and for clotting factor. 3. BHSF should provide a furnishing fee for clotting factor. 4. 340B program reimbursement for clotting factor Is inadequate.
Michael G. Griffin, President/CEO Daughters of Charity Health Centers	Medicaid Policy email account	1. The proposed rule regulates beyond the scope required by CMS to the detriment of our Health Centers and our patients. 2. This rule asserts, inappropriately, that covered entities must make the same carve-in or carve-out decision for FFS as it makes for Medicaid managed care. 3. An FQHC is a covered entity under the 340B Program by its mere designation.
Paul A. Salles, President & CEO Louisiana Hospital Association	Medicaid Policy email account	Concerned about how the proposed rule interfaces with the current outpatient hospital payment methodology.
Randal Johnson Louisiana Independent Pharmacies Association	Email to Medicaid Director	1. Requests clarification regarding the language of this Notice of Intent and the impact of any change in policy to current contract pharmacies and their patients. 2. Requests the Department revise the reimbursement methodology to include federal upper limits (FUL) new copayment exemptions and over-the-counter medications added for expansion benefits pursuant to recently released regulations from CMS. 3. Requests that the Department explain how the state determined the inclusion of the FUL in the

		reimbursement methodology, what is the fiscal impact of including FUL in the reimbursement methodology and how does the FUL compare to NADAC and LA-AAC. 4. Has concerns with the definition of the usual and customary charge. 5. Has questions regarding the cost savings calculation. 6. Wants to know the fiscal impact of these new Medicaid populations and what is the projected number of claims.

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

VIA ELECTRONIC MAIL ONLY

May 4, 2017

Morehouse Community Medical Centers
NO/AIDS Task Force d/b/a CrescentCare
Tulane University Health Sciences Center
Willis-Knighton Health System

To Whom It May Concern:

RE: Pharmacy Benefits Management Program Notice of Intent

This letter is in response to your correspondence regarding the Notice of Intent for Pharmacy Benefits Management Program which was published in the January 20, 2017 edition of the *Louisiana Register*.

This Notice of Intent amended the provisions governing the Pharmacy Benefits Management Program to comply with the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) Covered Outpatient Drugs Final Rule (CMS-2345-FC). CMS mandated that **fee-for-service (FFS)** outpatient drug reimbursement should be aligned with the acquisition cost of drugs and an appropriate professional dispensing fee. Specifically, the following were included:

- brand name drugs;
- generic drugs;
- back-up ingredient cost benchmark;
- 340B purchased drugs;
- 340B covered entities that purchase drugs outside of the 340B program;
- drugs acquired at the Federal Supply Schedule (FSS);
- drugs acquired at Nominal Price (outside of 340B or FSS);
- encounter rates;
- Federal Upper Limits (FULs);
- mail order drugs (such as specialty);
- long-term care facility drugs;
- physician administered drugs;
- clotting factor; and
- investigational drugs.

I would like to thank you for taking the time to provide comments regarding the proposed Rule. The Department has reviewed your comments, consulted with CMS and determined that further explanation should be provided on the following areas of your correspondence.

1. **"Remove language indicating that 340B covered entities must "carve out" Medicaid, and Medicaid managed care in particular, in contract pharmacy settings"**

   The proposed rule addresses only FFS Medicaid policy, not managed care organizations (MCOs).

   The Informational Bulletin 16-9, "340B Policy Clarification", stating 340B contract pharmacy carve-out across FFS and MCOs is a Medicaid policy to prevent duplicate discounts for Medicaid drug claims. Currently, the Medicaid rebate process uses the Health Resources and Services Administration's (HRSA) Medicaid Exclusion File to exclude providers wholly from rebate. Contract pharmacies are not permitted to bill Medicaid (FFS and MCOs) using 340B purchased drugs since the State does not have a mechanism in place to avoid duplicate discounts when both retail and 340B claims are submitted from the same pharmacy. This is not a new policy; the informational bulletin was posted for reference purposes. The informational bulletin will be revised again to clarify the use of claim level indicators.

2. **"Amend provisions that would require 340B covered entities to submit their actual acquisition cost (AAC) to Medicaid"**

   We have compared the Federal final rule to our current reimbursement methodology and determined that billing and reimbursement on 340B outpatient pharmacy claims must be modified. Covered entities shall bill and be reimbursed at actual acquisition cost for FFS outpatient drug claims. This does not include MCO outpatient pharmacy claims. Most states are moving to actual acquisition cost for FFS 340B pharmacy claims since this methodology would provide a clear audit trail.

   Reimbursement methodology for physician-administered drugs will remain the same. Outpatient hospital claims for physician-administered drugs will continue to be paid using a cost to charge methodology on the interim and are settled at cost during final settlement. Federally qualified health center (FQHC) and rural health clinic (RHC) claims for physician-administered drugs will be included in the all-inclusive T1015 encounter rate as they are currently.

3. **"Develop a 340B-specific professional dispensing fee, and work closely with stakeholders to ensure that any proposed reimbursement adequately covers the costs of handling and dispensing such drugs"**

Currently, FFS has one professional dispensing fee for all pharmacy claims. Professional dispensing fees will be reviewed and considered for specific circumstances in the future.

4. **"Consider alternatives for identifying covered entities that "carve in" and "carve out"**

   As stated above, the Medicaid rebate process uses the HRSA Medicaid Exclusion File to exclude providers wholly from rebate. As you pointed out, a provider level method has its disadvantages. The Department is in the process of requiring 340B covered entities to provide claim level indicators. Claim level indicators have disadvantages as well since not all claims can be identified as 340B at the time of service. The Department will continue to investigate and implement processes to address this issue possibly using a retrospective approach.

5. **"Correct inconsistencies between sections and an inaccurate reference."**

   Section 949.E. will be revised in the next amendment of the Pharmacy Rule to be consistent with Section 963.A. We agree that the language used in the proposed Rule needs greater clarification to ensure there are no inconsistencies.

   The definition of "contract pharmacy" in Section 961 will also be revised in the next amendment to the Pharmacy Rule to incorporate the 2010 HRSA language.

Should you have any questions or comments regarding Medicaid administrative rulemaking activity, you may contact Veronica Dent, Medicaid Program Manager, at (225) 342-3238 or by email to Veronica.Dent@la.gov.

Your continued cooperation and support of the Louisiana Medicaid Program efforts to coordinate care and improve health are greatly appreciated.

Sincerely,

Jen Steele
Medicaid Director

JS:LAO:DAB

c: Melwyn Wendt

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

May 4, 2017

L. Lee Hamm, M.D.
Tulane University Health Sciences Center School of Medicine
1430 Tulane Avenue, #8001
New Orleans, LA 70112-2699

Dear Dr. Hamm:

RE: Pharmacy Benefits Management Program Notice of Intent

This letter is in response to your correspondence regarding the Notice of Intent for Pharmacy Benefits Management Program which was published in the January 20, 2017 edition of the *Louisiana Register*.

This Notice of Intent amended the provisions governing the Pharmacy Benefits Management Program to comply with the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) Covered Outpatient Drugs Final Rule (CMS-2345-FC). CMS mandated that **fee-for-service (FFS)** outpatient drug reimbursement should be aligned with the acquisition cost of drugs and an appropriate professional dispensing fee. Specifically, the following were included:

- brand name drugs;
- generic drugs;
- back-up ingredient cost benchmark;
- 340B purchased drugs;
- 340B covered entities that purchase drugs outside of the 340B program;
- drugs acquired at the Federal Supply Schedule (FSS);
- drugs acquired at Nominal Price (outside of 340B or FSS);
- encounter rates;
- Federal Upper Limits (FULs);
- mail order drugs (such as specialty);
- long-term care facility drugs;
- physician administered drugs;
- clotting factor; and
- investigational drugs.

I would like to thank you for taking the time to provide comments regarding the proposed Rule. The Department has reviewed your comments, consulted with CMS and determined that further explanation should be provided on the following areas of your correspondence.

1. **"An Averaging Methodology Does Not Fulfill CMS' Directive and Does Not Approximate AAC"**

   The proposed rule addresses only FFS Medicaid policy, not managed care organizations (MCOs).

   We have compared the Federal final rule to our current reimbursement methodology and determined that billing and reimbursement on 340B outpatient pharmacy claims must be modified. Covered entities shall bill and be reimbursed at actual acquisition cost for FFS outpatient drug claims. The reimbursement methodology for all other drugs remains the same. The last reimbursement change in FFS was made in October 2014. Most drugs, including specialty drugs, long-term care facility drugs, and clotting factor are currently reimbursed at average acquisition cost (AAC), plus a professional dispensing fee ($10.41), plus the provider fee ($0.10). If no AAC is available, the drug is reimbursed at wholesaler acquisition cost (WAC), plus a professional dispensing fee ($10.41), plus the provider fee ($0.10). Most specialty drugs (not in the 340B program) in FFS are reimbursed at WAC for the ingredient component.

2. **"BHSF Must Establish a Separate Dispensing Fee for Specialty Pharmacies and for Clotting Factor"**

   The Department is in the process of evaluating future reimbursement changes, including hemophilia factor products. In a preliminary review of proposed changes, CMS did not require changing our current reimbursement methodology for specialty or clotting factor. If this change was made at this time, any substantive changes to the proposed Pharmacy Rule would compel the Department to publish a substantive changes notice and conduct a substantive changes public hearing, which would delay implementation of the Rule's provisions by an additional two to four months. With such change during this rulemaking process, we would not meet CMS' implementation date of April 1, 2017, which would cause the Department to be out of compliance with Federal regulations.

   Currently, FFS has one professional dispensing fee for all pharmacy claims. Professional dispensing fees will be reviewed and considered for specific circumstances in the future.

3. **"BHSF Should Provide a Furnishing Fee for Clotting Factor"**
   "340B Program Reimbursement for Clotting Factor Is Inadequate"

The Department is aware that handling and dispensing clotting factor includes costs that go far beyond traditional pharmacy services, and has a contractor reviewing costs associated with hemophilia treatment, and based on results, will consider future changes.

Should you have any questions or comments regarding Medicaid administrative rulemaking activity, you may contact Veronica Dent, Medicaid Program Manager, at (225) 342-3238 or by email to Veronica.Dent@la.gov.

Your continued cooperation and support of the Louisiana Medicaid Program efforts to coordinate care and improve health are greatly appreciated.

Sincerely,

Jen Steele
Medicaid Director

JS:LAO:DAB

c: Melwyn Wendt

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

May 4, 2017

Michael G. Griffin
Daughters of Charity Health Centers
P.O. Box 13038
New Orleans, LA 10178

Dear Mr. Griffin:

RE: Pharmacy Benefits Management Program Notice of Intent

This letter is in response to your correspondence regarding the Notice of Intent for Pharmacy Benefits Management Program which was published in the January 20, 2017 edition of the *Louisiana Register*.

This Notice of Intent amended the provisions governing the Pharmacy Benefits Management Program to comply with the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) Covered Outpatient Drugs Final Rule (CMS-2345-FC). CMS mandated that **fee-for-service (FFS)** outpatient drug reimbursement should be aligned with the acquisition cost of drugs and an appropriate professional dispensing fee. Specifically, the following were included:

- brand name drugs;
- generic drugs;
- back-up ingredient cost benchmark;
- 340B purchased drugs;
- 340B covered entities that purchase drugs outside of the 340B program;
- drugs acquired at the Federal Supply Schedule (FSS);
- drugs acquired at Nominal Price (outside of 340B or FSS);
- encounter rates;
- Federal Upper Limits (FULs);
- mail order drugs (such as specialty);
- long-term care facility drugs;
- physician administered drugs;
- clotting factor; and
- investigational drugs.

I would like to thank you for taking the time to provide comments regarding the proposed Rule. The Department has reviewed your comments, consulted with CMS and determined that further explanation should be provided on the following areas of your correspondence.

1. **"The proposed rule regulates beyond the scope required by CMS to the detriment of our Health Centers and our patients."**

   The proposed rule addresses only FFS Medicaid policy, not managed care organizations (MCOs).

   We have compared the Federal final rule to our current reimbursement methodology and determined that billing and reimbursement on 340B outpatient pharmacy claims must be modified. Covered entities shall bill and be reimbursed at actual acquisition cost for FFS outpatient drug claims. The reimbursement methodology for all other drugs remains the same. The last reimbursement change in FFS was October 2014. Most drugs including specialty drugs, long-term care facility drugs and clotting factor are currently reimbursed in FFS at average acquisition cost (AAC), plus a professional dispensing fee ($10.41), plus the provider fee ($0.10). If no AAC is available, the drug is reimbursed at wholesaler acquisition cost (WAC), plus a professional dispensing fee ($10.41), plus the provider fee ($0.10). Most specialty drugs (not in the 340B program) in FFS are reimbursed at WAC for the ingredient component.

2. **"This rule asserts, inappropriately, that covered entities must make the same carve-in or carve-out decision for FFS as it makes for Medicaid managed care."**

   The Rule addresses only FFS Medicaid policy, not policy directing reimbursement in the MCOs.

   The Informational Bulletin 16-9, "340B Policy Clarification", stating 340B contract pharmacy carve-out across FFS and MCOs is a policy to prevent duplicate discounts for Medicaid drug claims. Currently, the Medicaid rebate process uses the Health Resources and Services Administration's (HRSA) Medicaid Exclusion File to exclude providers wholly from rebate. Contract pharmacies are not permitted to bill Medicaid (FFS and MCOs) using 340B purchased drugs since the State does not have a mechanism in place to avoid duplicate discounts when both retail and 340B claims are submitted from the same pharmacy.

3. **"An FQHC is a covered entity under the 340B Program by its mere designation."**

This proposed Rule addresses only FFS Medicaid policy, not MCOs. Managed care organization reimbursements are made in accordance with contractual arrangements between the provider (340B covered entity) and the MCO.

Should you have any questions or comments regarding Medicaid administrative rulemaking activity, you may contact Veronica Dent, Medicaid Program Manager, at (225) 342-3238 or by email to Veronica.Dent@la.gov.

Your continued cooperation and support of the Louisiana Medicaid Program efforts to coordinate care and improve health are greatly appreciated.

Sincerely,

Jen Steele
Medicaid Director

JS:LAO:DAB

c: Melwyn Wendt

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

May 4, 2017

Paul A. Salles
Louisiana Hospital Association
9521 Brookline Avenue
Baton Rouge, LA 70809-1431

Dear Mr. Salles:

RE: Pharmacy Benefits Management Program Notice of Intent

This letter is in response to your correspondence regarding the Notice of Intent for Pharmacy Benefits Management Program which was published in the January 20, 2017 edition of the *Louisiana Register*.

This Notice of Intent amended the provisions governing the Pharmacy Benefits Management Program to comply with the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) Covered Outpatient Drugs Final Rule (CMS-2345-FC). CMS mandated that **fee-for-service (FFS)** outpatient drug reimbursement should be aligned with the acquisition cost of drugs and an appropriate professional dispensing fee. Specifically, the following were included:

- brand name drugs;
- generic drugs;
- back-up ingredient cost benchmark;
- 340B purchased drugs;
- 340B covered entities that purchase drugs outside of the 340B program;
- drugs acquired at the Federal Supply Schedule (FSS);
- drugs acquired at Nominal Price (outside of 340B or FSS);
- encounter rates;
- Federal Upper Limits (FULs);
- mail order drugs (such as specialty);
- long-term care facility drugs;
- physician administered drugs;
- clotting factor; and
- investigational drugs.

I would like to thank you for taking the time to provide comments regarding the proposed Rule. The Department has reviewed your comments, consulted with CMS and determined that further explanation should be provided regarding the following.

1. **"How would this proposed rule interface with the current outpatient hospital payment methodology?"**

   After further review and consultation with CMS, FFS outpatient hospital claims for 340B drugs should continue with the current payment methodology using a cost to charge methodology on the interim and being settled at cost during final settlement. The language in the proposed Rule will be clarified in the next amendment of the Pharmacy Rule.

   The Department shall implement claim level indicators to identify 340B drug claims to further prevent duplicate discounts. Informational Bulletin 16-9, "340B Policy Clarification", will be revised to include these requirements and provider notification will follow.

Should you have any questions or comments regarding Medicaid administrative rulemaking activity, you may contact Veronica Dent, Medicaid Program Manager, at (225) 342-3238 or by email to Veronica.Dent@la.gov.

Your continued cooperation and support of the Louisiana Medicaid Program efforts to coordinate care and improve health are greatly appreciated.

Sincerely,

Jen Steele
Medicaid Director

JS:LAO:DAB

c: Melwyn Wendt

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

May 4, 2017

Randal Johnson
Louisiana Independent Pharmacies Association
543 Spanish Town Road
Baton Rouge, LA 70802

Dear Mr. Johnson:

RE: Pharmacy Benefits Management Program Notice of Intent

This letter is in response to your correspondence regarding the Notice of Intent for Pharmacy Benefits Management Program which was published in the January 20, 2017 edition of the *Louisiana Register*.

This Notice of Intent amended the provisions governing the Pharmacy Benefits Management Program to comply with the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) Covered Outpatient Drugs Final Rule (CMS-2345-FC). CMS mandated that **fee-for-service (FFS)** outpatient drug reimbursement should be aligned with the acquisition cost of drugs and an appropriate professional dispensing fee. Specifically, the following were included:

- brand name drugs;
- generic drugs;
- back-up ingredient cost benchmark;
- 340B purchased drugs;
- 340B covered entities that purchase drugs outside of the 340B program;
- drugs acquired at the Federal Supply Schedule (FSS);
- drugs acquired at Nominal Price (outside of 340B or FSS);
- encounter rates;
- Federal Upper Limits (FULs);
- mail order drugs (such as specialty);
- long-term care facility drugs;
- physician administered drugs;
- clotting factor; and
- investigational drugs.

I would like to thank you for taking the time to provide comments regarding the proposed Rule. The Department has reviewed your comments, consulted with CMS and determined that further explanation should be provided regarding the following areas of your correspondence.

1. **"340B Contract Pharmacies"**

   The proposed rule addresses only FFS Medicaid policy, not managed care organizations (MCOs).

   The Informational Bulletin 16-9, "340B Policy Clarification", stating 340B contract pharmacy carve-out across FFS and MCOs is a Medicaid policy to prevent duplicate discounts for Medicaid drug claims. Currently, the Medicaid rebate process uses the Health Resources and Services Administration's (HRSA) Medicaid Exclusion File to exclude providers wholly from rebate. Contract pharmacies are not permitted to bill Medicaid (FFS and MCOs) using 340B purchased drugs since the State does not have a mechanism in place to avoid duplicate discounts when both retail and 340B claims are submitted from the same pharmacy. This is not a new policy; the informational bulletin was posted for reference purposes. The informational bulletin will be revised again to clarify the use of claim level indicators.

   Section 949.E. will be revised in the next amendment of the Pharmacy Rule to be consistent with Section 963.A. We agree that the language used in the proposed Rule needs greater clarification to ensure there are no inconsistencies.

   The definition of "contract pharmacy" in Section 961 will also be revised in the next amendment to the Pharmacy Rule to incorporate the 2010 HRSA language.

2. **"FUL"**

   Federal Upper Limits (FULs) are currently incorporated in the FFS "lower of" reimbursement methodology and have been since the 1990s. CMS has changed the basis of the FULs over the years and went many years without updating them. CMS recently updated the FULs in accordance with the Affordable Care Act. Since April 1, 2016, all previous FULs have been removed and replaced with the new FULs which are downloaded monthly as CMS releases them. Since FULs are already incorporated into the reimbursement methodology, there is no fiscal impact. CMS uses the most current monthly National Average Drug Acquisition Cost (NADAC) pricing files to calculate the FULs each month. The Department has requested a NADAC to average acquisition cost (AAC) comparison and it expecting to have results this month.

3. **"Usual and Customary"**

   As previously discussed, the Department is in agreement with a need to change the definition of *Usual and Customary* and will incorporate this change into the next amendment of the Pharmacy Rule.

4. **"Multiple AAC Issues"**

   340B invoices: Myers and Stauffer (M&S) has assured the Department that 340B invoices are not included in the calculation of AAC rates. 340B invoices are easily identified as outliers and are eliminated from the calculation process.

   AAC updates: Baseline AAC rates are calculated twice a year by M&S based on invoice costs submitted by Louisiana Medicaid pharmacies. To respond to changes in the marketplace, AAC rates are reviewed weekly for published pricing changes and daily when inquiries are received through the pharmacy help desk.

5. **"To obtain an AAC rate review between sampling periods, under current practice, was only available to pharmacies after Act 399 of the 2015 legislative session was passed and signed into law. This act provided pharmacies an avenue to appeal a claim for payment that was under reimbursed and below their cost by a Healthy Louisiana plan, and the avenue to review and AAC rate was borne from this as an operational necessity."**

   In FFS, M&S has performed provider rate reviews since 2010 when they began calculating LMAC rates for the Department. This process did not change in any significant way once the AAC was adopted in September 2012 or after. However, Act 399 of the 2015 Regular Session of the Louisiana Legislature addressed MCO reimbursement and provided "local" pharmacies a dispute process that the Department contracted M&S to operationalize, but this did not affect the AAC rate review that was previously in process.

6. **"Lastly, of the Department's intent to include new copayment exemptions and over-the-counter medications added for expansion benefits in their revision of the reimbursement methodology, with the inclusion of new exempted individuals, what is the fiscal impact of these new populations?"**

   The new copayment exemption and over-the-counter (OTC) medications added for expansion were implemented July 2016. This applies to FFS and MCOs to align prescription benefits and create continuity. Since this is current policy, there is no additional fiscal impact.

When a claim is exempt from copayment, the copayment is not subtracted from the reimbursement amount to the pharmacy. The pharmacy will not have a reduced payment if the recipient is unable to pay since there will not be a copayment to pay.

Should you have any questions or comments regarding Medicaid administrative rulemaking activity, you may contact Veronica Dent, Medicaid Program Manager, at (225) 342-3238 or by email to Veronica.Dent@la.gov.

Your continued cooperation and support of the Louisiana Medicaid Program efforts to coordinate care and improve health are greatly appreciated.

Sincerely,

Jen Steele
Medicaid Director

JS:LAO:DAB

c: Melwyn Wendt