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 ~~and Hospitals~~ reserves the right for ultimate decision making relative to

certain drug class information and drug contraindications or interactions.

C. ~~Formulary Management~~Covered Drug List. The ~~formulary~~ list of covered drugs is managed through ~~the use of Federal Upper Limits (FUL) and the Louisiana Maximum Allowable Costs (LMAC) limitations~~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 ~~and Louisiana Maximum Allowable Costs limitations~~ provide for dispensing of multiple source drugs at established limitations unless the prescribing ~~physician~~ practitioner specifies that the brand product is medically necessary for a patient. Establishment of co-payments also provides for ~~formulary~~ management. ~~The Medicaid Program has established a broad formulary with limited exceptions.~~

D. Reimbursement Management. The cost of pharmaceutical care is managed through ~~Estimated Acquisition Costs (EAC) of drug ingredient costs through~~ Average ~~Wholesale~~ Acquisition ~~Price~~ Cost (AAC) ~~(AWP) discounting, the Louisiana Maximum Allowable Costs (LMAC) limitations~~of the ingredient or through Wholesale Acquisition Cost (WAC) when no AAC is assigned, and compliance with ~~Federal Upper Limits (~~FUL~~)~~ regulations, and the

establishment of the ~~maximum allowable overhead costs~~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~~s~~ for on-going review ~~processes~~ for mis-utilization, abuse and fraud~~,~~ and audits of the pharmacy providers~~ of the Pharmacy Program~~.

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 ~~Plan~~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 ~~PRO-DUR~~prospective modules may screen for drug interactions, therapeutic duplication, improper

duration of therapy, incorrect dosages, clinical abuse/misuse and age restrictions. Electronic claims submission ~~sends on-line messages to~~inform pharmacists ~~informing them~~ of potential drug-related problems and ~~the~~ pharmacists ~~must~~ 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. ...

~~3. All Medicaid enrolled pharmacy providers whose claim volume exceeds 100 claims or $4,000 per month and all providers enrolled on January 1, 1996 will be required to participate in Point-of-Sale System. Long term care pharmacy provider claims may be processed through electronic media claims (EMC).~~

~~4. Providers accessing the POS/PRO-DUR system will be responsible for the purchase of all hardware for connection to the switching companies and any fees associated with connection or transmission of information to the fiscal intermediary. The Bureau of Health Services Financing will not reimburse the provider for any initial on-going fees incurred by the provider to access the POS/PRO-DUR system.~~I.3. – I.4. Repealed.

5. ~~Providers are required to verify eligibility with the monthly eligibility card and a copy of the card should be retained for processing the claim~~Eligibility verification is

determined at the point of sale.

6. Pharmacy providers and ~~physicians~~ prescribing providers may obtain assistance with clinical questions from the ~~Northeast Louisiana~~ University~~, School of Pharmacy~~ of Louisiana at Monroe.

7. ~~Physicians~~ 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 ~~physicians~~ 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 ~~shown on~~identified on each pharmacy claim ~~form~~ for reimbursement~~ of prescription drugs~~. 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 ~~prior~~ notice of termination of coverage~~ as required under federal regulations~~.

C. Prior Authorization with a Preferred Drug List

1. ~~As authorized by R.S. 46:153.3(B)(2)(a) and pursuant to 42 U.S.C. s1396r-8, a~~A prior authorization process is established which utilizes a preferred drug list (PDL) for selected therapeutic classes. ~~Drugs included on the PDL are automatically prior authorized.~~ Drugs in ~~those~~ selected therapeutic classes that are not included on the PDL shall require prescribers to obtain prior authorization. ~~Providers will be notified of the drugs selected for placement on the PDL by selected therapeutic classes prior to implementation of the prior authorization process and as additional drugs are subsequently~~

~~added to the list.~~ Lists of covered drug products, including those that require prior authorization, will be maintained ~~in either the Prescription Drug Services Manual, other designated service provider manuals,~~ on the Louisiana Medicaid web site ~~or provider notices~~.

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 ~~as mandated by R.S. 46:153.3(B)(2)(a) and pursuant to 42 U.S.C. s1396r-8~~.

3. ...

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

1. experimental drugs and investigational drugs;

2. ~~anorexics~~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 ~~(NOOH)~~, 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 because they are Aless than effective@ or Aidentical, related, or similar drugs@, and are identified as DESI ineffective drugs shall be excluded from coverage~~.

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 ~~and Hospitals~~, Bureau of Health Services Financing pays the full co-insurance and the Medicare deductible on pharmacy claims for services ~~provided~~ reimbursed by the Medicaid Program ~~to~~ 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 ~~individuals under 21 years of age~~pregnant women;

b. ~~services furnished to pregnant women if such services are related to the pregnancy, or to any other medical condition which may complicate the pregnancy~~emergency services;

c. ~~services furnished to any individual who is an inpatient in a hospital, long term care facility, or other medical institution~~family planning services; and

d. ~~emergency services provided in a hospital, clinic, physician office or other facility equipped to furnish emergency care~~preventive medications as designated by the U.S. Preventive Services Task Force's A and B recommendations;

e. ~~family planning services and supplies~~Repealed.

B. ~~In accordance with federal regulations, the~~The

following ~~provisions apply~~population groups are exempt from copayment requirements~~.~~:

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.~~individuals under the age of 21;

2. ~~Providers shall not waive the recipient copayment liability.~~individuals residing in a long-term care facility;

3. ~~Departmental monitoring and auditing will be conducted to determine provider compliance.~~individuals receiving hospice care;

4. ~~Violators of this §111 will be subject to a penalty such as suspension from the Medicaid Program.~~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. ...

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 ~~ICD-9-CM, or its successor,~~ diagnosis code

that is directly related to each drug prescribed that is over the four prescription limit (~~no ICD-9-CM, or its successor,~~ literal descriptions ~~is~~ are not acceptable).

D. – E. ...

F. An acceptable statement and ICD-~~9~~10-CM, or its successor, diagnosis code ~~is~~ are required for each prescription in excess of four ~~for that~~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 ~~physician~~ 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 ~~a narcotic~~methadone prescribed only for narcotic addiction.

5. – 5.c. ...

6. The prescribed drug is not a cosmetic drug, anorexic, cough and cold preparation, ~~minor tranquilizer,~~ or selected nonprescription drug ~~that is recommended for coverage by the Medicaid Drug Committee and approved by the department for reimbursement~~.

7. The prescribed drug is ~~included in the classification experimental drugs~~ not an experimental or investigational drug which are generally labeled: ~~A~~Caution - limited by federal law to investigational use,@ unless a specific exception has been granted by the federal government ~~and the prescription drug has been recommended for coverage by the Medicaid Drug Program Committee and approved by the department~~.

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. ~~A complete listing of covered drugs will be maintained in the Title XIX provider manual for utilization by providers.~~ 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 ~~Medical Assistance~~ 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. ~~Erectile Dysfunction~~

~~drugs shall only be covered for the treatment of conditions other than sexual or erectile dysfunction for which the drugs have been approved by the Food and Drug Administration.~~

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 ~~physician~~ licensed prescriber. ~~or other service practitioner covered under the Medicaid Program and~~These prescriptions shall not be refilled ~~not~~ 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 ~~and shall be refilled not more than five times in six months~~. 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 ~~and Hospitals~~ 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 ~~and Hospitals~~, 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~~Lock-~~in~~ 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~~Lock-~~in~~ 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~~H~~ 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~~H~~'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~~Lock-~~in~~ In provider(s) request(s) that the

recipient be transferred; or

4. the ~~lock~~Lock-~~in~~ 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~~Lock-~~in~~ In for pharmacy and physician services. No recipient on ~~lock~~Lock-~~in~~ 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~~Lock-~~in~~ 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 ~~six months~~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. ~~Parenteral nutrition is covered for a recipient with permanent, severe pathology of the alimentary tract which does~~

~~not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the recipient's general condition~~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

~~A. Parenteral nutrition will be denied as noncovered in situations involving temporary impairments. The recipient must have:~~

~~1. a condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients; or~~

~~2. a disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through the GI system. There must be objective evidence supporting the clinical diagnosis.~~

~~B. Parenteral nutrition is noncovered for the recipient with a functioning gastrointestinal tract whose need for~~

~~parenteral nutrition is only due to:~~

~~1. a swallowing disorder;~~

~~2. a temporary defect in gastric emptying such as a metabolic or electrolyte disorder;~~

~~3. a psychological disorder impairing food intake such as depression;~~

~~4. a metabolic disorder inducing anorexia such as cancer;~~

~~5. a physical disorder impairing food intake such as the dyspnea of severe pulmonary or cardiac disease;~~

~~6. a side effect of a medication; or~~

~~7. renal failure and/or dialysis.~~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. ~~However, Medicaid will pay for no more than one month's supply of nutrients at any one time. All requests to the PAU shall include:~~

~~1. the prognosis as well as the diagnosis;~~

~~2. the date the recipient was first infused;~~

~~3. whether the recipient has been trained to use parenteral equipment;~~

~~4. a statement that the recipient is capable of operating the parenteral equipment;~~

~~5. either the Medicaid certificate of medical necessity form for TPN, or the Medicare certificate of medical necessity form, Form DMERC 10.02A, completed and signed by the treating physician;~~

~~6. documentation showing that the recipient has a permanent impairment. Permanence does not require a determination that there is no possibility that the recipient's condition may improve sometime in the future. Medical documentation must substantiate that the condition is expected to last a long and indefinite duration (at least three months).~~

~~B. Additional documentation must be included with the initial request for parenteral nutrition.~~

~~1. In the situations addressed in B.1-4 under medical necessity criteria, the documentation must include copies of the operative report and/or hospital discharge summary and/or x-ray reports and/or a physician letter which document the condition and the necessity for PN therapy.~~

~~2. For the situations addressed in B.5 and D.2 under~~

~~medical necessity criteria (when appropriate), include the results of the fecal fat test and dates of the test.~~

~~3. For the situations addressed in B.6 and D.2 under medical necessity criteria, include a copy of the report of the small bowel motility study and a list of medications that the recipient was on at the time of the test.~~

~~4. For the situations addressed in B.5 – D.2 under medical necessity criteria, include the results of serum albumin and the date of the test (within one week prior to initiation of PN) and a copy of a nutritional assessment by a physician, dietitian or other qualified professional within one week prior to initiation of PN, to include the following information:~~

~~a. current weight with date and weight one – three months prior to initiation of PN;~~

~~b. estimated daily calorie intake during the prior month and by what route (e.g., oral, tube);~~

~~c. statement of whether there were caloric losses from vomiting or diarrhea and whether these estimated losses are reflected in the calorie count;~~

~~d. description of any dietary modifications made or supplements tried during the prior month (e.g., low fat, extra medium chain triglycerides, etc.).~~

~~5. For situations described in D.2 under medical necessity criteria, include:~~

a. a statement from the physician;

b. copies of objective studies; and

c. excerpts of the medical record giving the following information:

i. specific etiology for the gastroparesis, small bowel dysmotility, or malabsorption;

ii. a detailed description of the trial of tube enteral nutrition including the beginning and ending dates of the trial, duration of time that the tube was in place, the type and size of tube, the location of tip of the tube, the name of the enteral nutrient, the quantity, concentration, and rate of administration, and the results;

iii. a copy of the x-ray report or procedure report documenting placement of the tube in the jejunum;

iv. prokinetic medications used, dosage, and dates of use;

v. nondietary treatment given during prior month directed at etiology of malabsorption (e.g., antibiotic for bacterial overgrowth); and

vi. any medications used that might impair GI tolerance to enteral feedings (e.g., anticholinergics, opiates, tricyclics, phenothiazines, etc.) or that might interfere with test results (e.g., mineral oil, etc.) and a statement explaining the need for these medications.

~~6. Any other information which supports the medical necessity for parenteral nutrition may also be included.~~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. In order to cover IDPN, documentation must be clear and precise to verify that the recipient suffers from a permanently impaired gastrointestinal tract and that there is insufficient absorption of nutrients to maintain adequate strength and weight. The supporting documentation must substantiate that the recipient cannot be maintained on oral or enteral feedings and that due to severe pathology of the alimentary tract, the recipient must be intravenously infused with nutrients.~~

~~C. Infusions must be vital to the nutritional stability of~~

~~the recipient and not supplemental to a deficient diet or deficiencies caused by dialysis. Physical signs, symptoms and test results indicating severe pathology of the alimentary tract must be clearly evident in any documentation submitted. Recipients receiving IDPN must also meet the criteria for parenteral nutrition.~~

~~D. If the medical necessity criteria for parenteral nutrition are met, one supply kit and one administration kit will be covered for each day that parenteral nutrition is administered, if such kits are medically necessary and used.~~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

~~A. For the initial request and for revised requests or reconsiderations involving a change in the order, there must be additional documentation to support the medical necessity of the following orders, if applicable:~~

~~1. the need for special nutrients;~~

~~2. the need for dextrose concentration less than 10~~

~~percent;~~

~~3. the need for lipids more than 15 units of a 20 percent solution or 30 units of a 10 percent solution per month.~~

~~B. After the first six months, the PA request must include a physician's statement describing the continued need for parenteral nutrition. For situations described in B.5-D.2 under medical necessity criteria, the PA request must include the results of the most recent serum albumin (within two weeks of the request date) and the recipient's most recent weight with the date of each. If the results indicate malnutrition, there should be a physician's statement describing the continued need for parenteral nutrition and any changes to the therapeutic regimen that are planned.~~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. ...

~~1. An external ambulatory infusion pump is a small portable electrical device that is used to deliver parenteral nutrition. It is designed to be carried or worn by the~~

~~recipient.~~

~~2. A stationary infusion pump is an electrical device, which serves the same purpose as an ambulatory pump, but is larger and typically mounted on a pole.~~

~~B. An IV pole is a device to suspend fluid to be administered by gravity or pump. An IV pole will be covered when a recipient is receiving parenteral fluids and the recipient is not using an ambulatory infusion pump.~~

~~C. Infusion pumps, ambulatory and stationary, are indicated for the administration of parenteral medication in the home when parenteral administration of the medication in the home is reasonable and medically necessary, and an infusion pump is necessary to safely administer the medication.~~

~~D. An external ambulatory infusion pump is a small portable electrical device that is used to deliver parenteral medication. It is designed to be carried or worn by the recipient.~~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—~~the wholesale price of a drug product as reported to the agency by one or more national compendia on a weekly basis to update the Medicaid Management Information System (MMIS)~~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. ~~Average Wholesale Price~~Estimated Acquisition Cost

§935. Estimated Acquisition Cost Formula

A. *Estimated Acquisition Cost (EAC)* is the ~~modified~~ average ~~wholesale price~~acquisition cost of the drug dispensed~~, identified by the manufacturer number, product number, and package number usually purchased by a provider, from a supplier whose products are generally available to all pharmacies and~~

~~reported in one or more national compendia. Repackaged drug products supplied through co-ops, franchises, or other sources not readily available to other providers shall not be used to estimate provider acquisition cost. In such instances, the average wholesale price for the drug product used by the repackager identified by the manufacturer number, product number, and largest reported package size in one or more national compendia shall be utilized by the agency to estimate acquisition cost~~. 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. ~~The agency shall make payments for multiple source drugs other than drugs subject to "physician certifications" based on the lower of:~~

~~1. Average Wholesale Price (AWP) minus 13.5 percent for independent pharmacies and AWP minus 15 percent for chain pharmacies. This applies to:~~

~~a. single source drugs;~~

~~b. multiple source drugs that do not have a state maximum allowable cost (MAC) or federal upper limit; and~~

~~c. those prescriptions subject to MAC overrides based on the physician's certification that a brand name product is medically necessary;~~

~~2. Louisiana's maximum allowable cost limitation plus the maximum allowable overhead cost;~~

~~3. federal upper limits plus the maximum allowable overhead cost; or~~

~~4. provider's usual and customary charges to the general public. *General Public* is defined here as all other non-Medicaid prescriptions including:~~

~~a. third-party insurance;~~

~~b. pharmacy benefit management; and~~

~~c. cash.~~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. ~~Each pharmacy's records shall establish that the established dispensing fee paid by the Medical Assistance Program for prescription does not exceed the dispensing fee paid by others. This also applies to the payment for insulin and diabetic testing agency and indwelling catheters and catheterization trays for which the dispensing fee may not exceed 50 percent of the wholesale price~~Repealed.

B. Payment will be made for medications in accordance with the payment procedures for any fee-for-service (FFS) Medicaid eligible person~~ who has identified himself to the provider by presenting his identification card which shows his eligibility~~. On a periodic basis as ingredient costs change, the department will post a link on its website containing average acquisition cost of drugs. ~~State office advises participating pharmacists regarding payable medication.~~

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 ~~licensed physician or dentist~~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

~~the Medical Assistance Program's~~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 ~~or the name of his own clinic or hospital)~~ 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 ~~the Medical Assistance Program~~Medicaid for medications he dispenses, he shall certify that he himself, ~~another prescriber,~~ 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. ~~Federal Upper Limits for Multiple Source Drugs~~Brand Drugs. The department shall make payments for single source drugs (brand drugs) based on the lower of:

1. ~~Except for drugs subject to "Physician Certification", the Medical Assistance Program shall utilize listings established by CMS that identify and set upper limits for multiple source drugs that meet the following requirements.~~average acquisition cost (AAC):

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).~~If no AAC is available, use the wholesale acquisition cost (WAC) plus the professional dispensing fee; or

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~~Repealed.

2. ~~The~~ the ~~Medical Assistance Program shall utilize the maximum acquisition cost established by CMS in determining Multiple Source Drug Cost~~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.

~~3. The Medical Assistance Program shall provide pharmacists who participate in Title XIX 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.~~A.3. – A.3.c. Repealed.

B. ~~Louisiana Maximum Allowable Cost (LMAC) Limits~~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. ~~LMAC is the median AWP cost for a specific strength/unit drug determined by listing the wholesale costs for each readily available manufacturer, labeler, etc., and taking the median of those AWP costs (one-half will be above the median cost and one-half will be below the median cost). LMAC limits may be adjusted by the agency based on changes in the availability and estimated acquisition costs (EAC) of the drugs.~~AAC:

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

2. ~~The agency shall make determinations of which multiple source drugs are to be subject to LMAC regulation based on the availability of drugs in the Louisiana Medical Assistance Program. The availability of a drug product will be determined by review of provider claim data. Providers shall be given~~

~~advanced notice of any additions, deletions, or adjustments in price. Any provider may request and receive at no charge, one complete listing annually.~~federal upper payment limits plus the professional dispensing fee; or

3. ~~In no case shall a recipient be required to provide payment for any difference in a prescription price that may occur with implementation of the LMAC limit, nor may BHSF use a cost which exceeds the established maximums except for physician certification for brand name drugs.~~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. ~~Lower of Reimbursement for Multiple Source Drugs~~Federal Upper Payment Limits for Multiple Source Drugs~~. The agency shall make payments for Multiple Source Drugs other than drugs subject to *physician certifications* based on the lower of:~~

1. ~~the providers' usual and customary charges to the general public not to exceed the agency's "Maximum Pharmaceutical Price Schedule;~~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. ~~the agency's estimate of acquisition cost plus the agency's established dispensing fee;~~Medicaid shall utilize the maximum acquisition cost established by CMS in determining multiple source drug cost.

3. ~~any applicable Federal Upper Limit for Multiple Source Drugs plus the agency's established dispensing fee; or~~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. ~~any applicable Louisiana Maximum Allowable Cost limit plus the agency's established dispensing fee~~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. ~~Other Drug Cost Limits~~340B Purchased Drugs. The ~~agency~~ department shall make payments for drugs ~~other than multiple source drugs and drugs subject to APhysician Certifications@ based on the lower of:~~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.

~~1. the agency's estimate of acquisition cost plus the agency's established dispensing fee;~~

~~2. the providers' usual and customary charges to the general public not to exceed the agency's AMaximum Pharmaceutical Price Schedule@.~~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~~, after taking into account such items as purchasing allowances, discounts, wholesaler fees and rebates~~.

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 ~~may also serve as billing agents~~

~~for covered entities~~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——~~the fee paid by Medicaid for the professional services provided by a pharmacist when dispensing a prescription, including the $.10 provider fee assessed for each prescription filled in the State of Louisiana per legislative mandate~~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 ~~such~~ 340B drugs should not be billed to

Medicaid. All other drugs shall be billed in accordance with existing ~~state~~ Louisiana Medicaid reimbursement methodologies. Indian Health Service, tribal and urban Indian pharmacy claims will be reimbursed in the encounter rate.

B. Contract Pharmacies. ~~In the event that the covered entity has entered into a contract pharmacy arrangement and the contract pharmacy serves as the covered entity's billing agent, the contract pharmacy shall bill Medicaid at actual acquisition cost under the covered entity's Medicaid pharmacy billing number, unless the covered entity has implemented the Medicaid carve-out option, in which case such drugs shall be billed in accordance with existing state Medicaid reimbursement methodologies under the contract pharmacy's Medicaid pharmacy billing number~~Contract pharmacies are not allowed to bill 340B drugs to Medicaid; therefore, they should carve out.

C. Professional Dispensing Fees. The covered entity ~~shall~~ will be ~~paid a dispensing fee of $8.10 for each prescription dispensed to a Medicaid patient, unless the covered entity has implemented the carve-out option, in which case the covered entity shall be paid the state's existing maximum allowable overhead cost. With respect to contract pharmacy arrangements in which the contract pharmacy also serves as the covered entity's billing agent, the contract pharmacy shall be paid the $8.10 dispensing fee on behalf of the covered entity, unless the~~

~~covered entity elects the Medicaid carve-out, in which case the contract pharmacy shall be paid the state's existing maximum allowable overhead cost~~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~~ program and dispensed to Medicaid recipients shall be billed to Medicaid at actual acquisition cost ~~plus 10 percent~~ and the professional dispensing fee ~~unless the covered entity has implemented the Medicaid carve-out option~~. ~~If the covered entity has implemented the Medicaid carve-out option, such drugs shall be reimbursed at AWP minus 30 percent plus the dispensing fee or the billed charges, whichever is less.~~

B. ~~Anti-hemophilia drugs purchased by a non-340B covered entity shall be reimbursed at AWP minus 30 percent plus the dispensing fee or the billed charges, whichever is less~~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