

**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. The Louisiana Medicaid Pharmacy Benefits Management System (LMPBM) includes a Point-of-Sale/Prospective Drug Utilization Review component.

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. National average drug acquisition cost (NADAC) 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 NADAC of the ingredient or through wholesale acquisition cost (WAC) when no NADAC is assigned, and compliance with FUL regulations, the establishment of the professional dispensing fee, drug rebates and copayments. Usual and customary charges are compared to other reimbursement methodologies and the "lesser of" is reimbursed.

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

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

1. retrospective drug utilization review;
2. Lock-In Program for patient education;
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. Pharmacy Provider Network. Enrolled Medicaid pharmacy providers are required to comply with all applicable federal and state laws and regulations.

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 therapeutic modules in accordance with the standards of the National Council of Prescription Drug Programs. The purpose of prospective drug utilization review is to reduce duplication of drug therapy, prevent drug-to-drug interactions, and assure appropriate drug use, dosage and duration. The prospective modules may screen for drug interactions, therapeutic duplication, improper duration of therapy, incorrect dosages, clinical abuse/misuse and age restrictions. Electronic claims submission inform pharmacists of potential drug-related problems and pharmacists document their responses by using interventions codes. By using these codes, pharmacists will document prescription reporting and outcomes of therapy for Medicaid recipients.

I. POS/PRO-DUR Requirements Provider Participation

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

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

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

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

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

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

L. Peer Counseling and Conference Management. The department will analyze data for individual prescribers and pharmacists. Quality management strategies will be used for peer counseling and conferences with prescribers and/or

pharmacists to assure appropriate prescribing and dispensing.

**AUTHORITY NOTE:** Promulgated in accordance with R.S. 36:254, Title XIX of the Social Security Act, and the 1995-96 General Appropriate Act.

**HISTORICAL NOTE:** Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1053 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1180 (June 2017), LR 43:1553 (August 2017), LR 45:570 (April 2019), amended LR 45:665 (May 2019).

### §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. The Pharmaceutical and Therapeutics Committee will make recommendations to the Department regarding drugs to be considered for prior authorization. The composition of and appointment to the Pharmaceutical and Therapeutics Committee complies with R.S. 46:153.3(D) and 42 U.S.C.s1396r-8.

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. compounded prescriptions (mixtures of two or more ingredients-the individual drugs will continue to be reimbursed);

6. medications which are included in the reimbursement to a facility, i.e.:

- a. hospitals;
- b. skilled nursing facility for recipients receiving benefits under Part A of Title XVIII;
- c. mental hospitals; or
- d. some other nursing facilities;

7. non-legend drugs with some exceptions;

8. fertility drugs when used for fertility treatment;

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

10. DESI Drugs (see Subsection E below).

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, Title XIX of the Social Security Act, and the 1995-96 General Appropriate Act.

**HISTORICAL NOTE:** Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1053 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1180 (June 2017), LR 43:1553 (August 2017), amended LR 45:665 (May 2019).

### §109. Medicare Part B

A. The Department of Health, Bureau of Health Services Financing pays the full co-insurance and the Medicare deductible on outpatient 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. 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 32:1055 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1181 (June 2017), LR 43:1553 (August 2017)

### §111. Copayment

#### A. Payment Schedule

1. A copayment requirement in the Pharmacy Program is based on the following payment schedule.

Calculated State Payment	Copayment
\$10.00 or less	\$0.50
\$10.01 to \$25.00	\$1.00
\$25.01 to \$50.00	\$2.00
\$50.01 or more	\$3.00

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.

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 and Alaskan Eskimos;
5. women whose basis for Medicaid eligibility is breast or cervical cancer; and
6. home and community-based services 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. 36:254 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 43:1181 (June 2017), LR 43:1553 (August 2017).

### **§113. Prescription Limit**

A. Effective February 1, 2011, the Department of Health and Hospitals will pay for a maximum of four prescriptions per calendar month for Medicaid recipients.

B. The following federally mandated recipient groups are exempt from the four prescriptions per calendar month limitation:

1. persons under 21 years of age;

2. persons who are residents of long-term care institutions, such as nursing homes and ICF-DD facilities; and

3. pregnant women.

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. "medically necessary override;" and

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. The prescriber should use the Clinical Drug Inquiry (CDI) internet web application developed by the fiscal intermediary in his/her clinical assessment of the patient's disease state or medical condition and the current drug regime before making a determination that more than four prescriptions per calendar month is required by the recipient.

E. Printed statements without the prescribing practitioner's signature, check-off boxes or stamped signatures are not acceptable documentation.

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. Pharmacists and prescribers are required to maintain documentation to support the override of a prescription limitation.

**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 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 43:1181 (June 2017).

### **§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. The prescribed drug has been approved and designated as safe and effective by the Food and Drug Administration.

2. The prescribed drug is not classified as a DESI drug (drugs which have been identified by the FDA as lacking evidence of safety/effectiveness).

3. The prescribed drug is not a compounded prescription (mixtures of two or more ingredients).

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

5. The prescription is not for medications which are included in the reimbursement to Title XIX facilities, including, but not limited to:

- a. hospitalized recipients;
- b. recipients receiving benefits under Part A of Title XVIII in a skilled nursing facility; or
- c. resident/patients at Villa Feliciana or any state mental hospital.

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 immunosuppressant 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. 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 32:1055 (June 2006), LR 32:2083

(November 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1182 (June 2017).

#### §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. Transferring Prescriptions. Transfer of a prescription from one pharmacy to another is allowed if less than one year has passed since the date prescribed and in accordance with the Louisiana Board of Pharmacy requirements. Transfer of a prescription for a controlled substance in schedule III, IV and V from one pharmacy to another is allowed if less than six months has passed since the date prescribed, and transfer of a prescription for a controlled substance in Schedule II is not allowed. Transfers of prescriptions shall be allowed in accordance with the Louisiana Board of Pharmacy regulations.

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 32:1056 (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 43:1182 (June 2017).

#### §119. Maximum Quantity

A. For all prescriptions, the maximum quantity payable shall be a month's supply or 100 unit doses, whichever is greater. The quantity billed shall be that prescribed, unless it exceeds the maximum quantity payable in which case the maximum quantity payable shall be filled.

B. When maintenance drugs are prescribed and dispensed for chronic illnesses they shall be in quantities sufficient to effect economy in dispensing and yet be medically sound. Listed below are drugs the agency considers to be maintenance type drugs and which should be prescribed and dispensed in a month's supply:

- 1. anti-coagulants;
- 2. anti-convulsants;
- 3. oral anti-diabetics;
- 4. calcium gluconate, calcium lactate, and calcium phosphate;

## 5. cardiovascular drugs including:

- a. diuretics;
- b. antihypertensives; and
- c. antihyperlipidemics;

## 6. estrogens;

## 7. ferrous gluconate and ferrous sulfate;

## 8. potassium supplements;

## 9. thyroid and antithyroid drugs;

## 10. Vitamins

- a. A, D, K, B<sub>12</sub> injection;
- b. Folic Acid; and
- c. Nicotinic Acid.

C. For patients in nursing homes, the pharmacist shall bill for a minimum of a month's supply of medication unless the treating physician specifies a smaller quantity for a special medical reason.

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. 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 32:1056 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1182 (June 2017).

### §123. Medication Administration

A. Influenza Vaccine Administration. The department shall provide coverage for administration of the influenza vaccine by a qualified pharmacist when:

- 1. the pharmacist has been credentialed by the Louisiana Board of Pharmacy to administer medications; and
- 2. the pharmacist is Medicaid-enrolled.

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, LR 36:1783 (August 2010), amended LR 40:82 (January 2014).

## Chapter 3. Lock-In Program

### §301. Introduction

A. Recipients shall have free choice of pharmacy unless subject to the agency's Lock-In program.

B. Lock-in is a mechanism for restricting Medicaid recipients to a specific physician and/or a specific pharmacy provider. The lock-in mechanism does not prohibit the recipient from receiving services from providers who offer services other than physician and pharmacy benefits. The lock-in mechanism:

1. ensures appropriate use of Medicaid benefits by recipients and/or providers; and

2. serves as an educational and monitoring parameter in instructing recipients in the most efficient method of using Medicaid services to ensure maximum health benefits.

C. A Medicaid recipient who has shown a consistent pattern of misuse or overuse of program benefits may be placed into the lock-in mechanism. Misuse and overuse is a determination made by the Department of Health and Hospitals, Bureau of Health Services Financing. Misuse and overuse can occur in a variety of ways.

1. Misuse may take the form of obtaining prescriptions under the pharmacy program from various prescribers and/or pharmacies in an uncontrolled and unsound way.

2. Misuse may take the form of obtaining prescriptions or the dispersal of prescriptions by fraudulent actions.

D. The Bureau of Health Services Financing or its medical designee shall be responsible to determine when a recipient should be enrolled in lock-in.

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 32:1056 (June 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:3268 (November 2011).

### §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. 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 32:1057 (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 43:1182 (June 2017).

### §307. Notification Directives

A. The department's contract designee shall notify the recipient of the decision to lock-in providers and shall include the following additional information:

1. the department's intention to allow the recipient to choose one primary care provider, one pharmacy provider, and up to three specialist providers, if warranted;

2. that Medicaid will make payments only to the physician and pharmacy providers chosen by the recipient and subsequently approved by the department;

3. that the recipient is advised to contact the department's contract designee to discuss the Pharmacy Lock-In Program; and

4. that the recipient has the right to appeal the initial lock-in decision.

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. assist the recipient, if necessary, in exercising due process rights and complete the appropriate forms at the initial contact; and

4. notify Lock-In providers of their selection.

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 32:1057 (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 43:1182 (June 2017).

### **§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.

1. In order to be approved as a Lock-In provider, the physician or pharmacy shall accept Medicaid as reimbursement for services rendered. Recipients are prohibited from paying cash for services rendered.

B. A recipient loses freedom of choice of providers once the lock-in decision has been made. Only the initial lock-in decision can be appealed. Provider selection is not appealable.

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 32:1057 (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 43:1183 (June 2017).

### **§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. 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 32:1057 (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 43:1183 (June 2017).

### **§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. a recipient relocates;
2. a recipient's primary diagnosis changes;
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. 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 and Hospitals, Bureau of Health Services Financing, LR 37:3269 (November 2011), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1183 (June 2017).

### **§315. Recipient Profile Review**

A. Recipients profiles are to be reviewed periodically as described in the Lock-In Procedure Manual (for determination of continuance or discontinuance of lock-in). The department's medical designee(s) examine(s) a recipient's profile for a continued pattern of misuse or overuse of program benefits. Periods of ineligibility for Medicaid will not affect the lock-in status of the individual. A review at the end of the first four months of ineligibility of lock-in closure will be made to determine if lock-in should be continued. Based upon a recommendation of the department's medical designee, a decision may be made to restore unrestricted benefits and appropriate notification will be provided to the recipient.

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 and Hospitals, Bureau of Health Services Financing, LR 37:3269 (November 2011).

## **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 43:1183 (June 2017).

## **Chapter 7. Parenteral Nutrition Therapy**

### **§701. Introduction**

A. Parenteral nutrition (PN) therapy is the introduction of nutrients by some means other than through the gastrointestinal tract, in particular intravenous, subcutaneous, intramuscular, or intramedullary injection. Intravenous nutrition is also referred to as TPN (Total Parenteral Nutrition) or Hyperalimentation Therapy.

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).

### **§703. Medical Necessity**

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

B. Parenteral nutrition is considered to be medically necessary when any of the following conditions exists. The conditions must be deemed to be severe enough that the recipient would not be able to maintain his/her weight and strength on only oral intake or tube enteral nutrition. The recipient:

1. has undergone recent (within the past three months) massive small bowel resection leaving less than or equal to 5 feet of small bowel beyond the ligament of Treitz; or
2. has a short bowel syndrome that is severe enough that the recipient has net gastrointestinal fluid and electrolyte malabsorption such that on an oral intake of 2.5-3 liters/day the enteral losses exceed 50 percent of the oral/enteral intake and the urine output is less than 1 liter/day; or
3. requires bowel rest for at least three months and is receiving intravenously 20-35 cal/kg/day for treatment of symptomatic pancreatitis with/without pancreatic pseudocyst, severe exacerbation of regional enteritis, or a proximal enterocutaneous fistula where tube feeding distal to the fistula is not possible; or
4. has complete mechanical small bowel obstruction where surgery is not an option; or
5. is significantly malnourished (10 percent weight loss over three months or less and serum albumin less than or equal to 3.4 gm/dl) and has very severe fat malabsorption (fecal fat exceeds 50 percent of oral/enteral intake on a diet of at least 50 gm of fat/day as measured by a standard 72 hour fecal fat test); or
6. is significantly malnourished (10 percent weight loss over three months or less and serum albumin less than or equal to 3.4 gm/dl) and has a severe motility disturbance of the small intestine and/or stomach which is unresponsive to prokinetic medication. Prokinetic medication is defined as the presence of daily symptoms of nausea and vomiting while taking maximal doses and is demonstrated either:

a. scintigraphically (solid meal gastric emptying study demonstrates that the isotope fails to reach the right colon by six hours following ingestion); or

b. radiographically (barium or radiopaque pellets fail to reach the right colon by six hours following administration).

NOTE: These studies must be performed when the recipient is not acutely ill and is not on any medication which would decrease bowel motility.

C. Maintenance of weight and strength commensurate with the recipient's overall health status must require intravenous nutrition and must not be possible utilizing all of the following approaches:

1. modifying the nutrient composition of the enteral diet (e.g., lactose free, gluten free, low in long chain triglycerides, substitution with medium chain triglycerides, provision of protein as peptides or amino acids, etc.); and

2. utilizing pharmacologic means to treat the etiology of the malabsorption (e.g., pancreatic enzymes or bile salts, broad spectrum antibiotics for bacterial overgrowth, prokinetic medication for reduced motility, etc.).

D. Recipients who do not meet the criteria in B.1-6 must meet criteria in C.1-2 (modification of diet and pharmacologic intervention) in addition to the following criteria:

1. the recipient is malnourished (10 percent weight loss over three months or less and serum albumin less than or equal to 3.4 gm/dl); and

2. a disease and clinical condition has been documented as being present and it has not responded to altering the manner of delivery of appropriate nutrients (e.g., slow infusion of nutrients through a tube with the tip located in the stomach or jejunum).

E. The following are some examples of moderate abnormalities which would require a failed trial of tube enteral nutrition before PN would be covered:

1. moderate fat malabsorption - fecal fat exceeds 25 percent of oral/enteral intake on a diet of at least 50 gm fat/day as measured by a standard 72 hour fecal fat test;

2. diagnosis of malabsorption with objective confirmation by methods other than 72 hour fecal fat test (e.g., Sudan stain of stool, dxylose test, etc.);

3. gastroparesis which has been demonstrated:

a. radiographically or scintigraphically as described in Subsection B above with the isotope or pellets failing to reach the jejunum in three to six hours; or

b. by manometric motility studies with results consistent with an abnormal gastric emptying, and which is unresponsive to prokinetic medication;

4. a small bowel motility disturbance which is unresponsive to prokinetic medication, demonstrated with a gastric to right colon transit time between three to six hours;

5. small bowel resection leaving greater than 5 feet of small bowel beyond the ligament of Treitz;

6. short bowel syndrome which is not severe (as defined in B.2);

7. mild to moderate exacerbation of regional enteritis, or an enterocutaneous fistula;

8. partial mechanical small bowel obstruction where surgery is not an option.

F. Documentation must support that a concerted effort has been made to place a tube. For gastroparesis, tube placement must be post-pylorus, preferably in the jejunum. Use of a double lumen tube should be considered. Placement of the tube in the jejunum must be objectively verified by radiographic studies or fluoroscopy. Placement via endoscopy or open surgical procedure would also verify location of the tube.

G. A trial with enteral nutrition must be documented, with appropriate attention to dilution, rate, and alternative formulas to address side effects of diarrhea.

H. PN can be covered in a recipient with the ability to obtain partial nutrition from oral intake or a combination of oral/enteral or oral/enteral/parenteral intake as long as the following criteria are met:

1. a permanent condition of the alimentary tract is present which has been deemed to require parenteral therapy because of its severity;

2. a permanent condition of the alimentary tract is present which is unresponsive to standard medical management; and

3. the person is unable to maintain weight and strength.

I. If the medical necessity criteria for parenteral nutrition are met, medically necessary nutrients, administration supplies and equipment are covered. PN solutions containing little or no amino acids and/or carbohydrates would be covered only in situations stated in B.1, 2, or 4 above.

#### J. Documentation Requirements

1. Recipients covered under Paragraph B.4 must have documentation of the persistence of their condition. Recipients covered under B.5-D.2 must have documentation that sufficient improvement of their underlying condition has not occurred which would permit discontinuation of parenteral nutrition. Coverage for these recipients would be continued if the treatment has been effective as evidenced by an improvement of weight and/or serum albumin. If there has been no improvement, subsequent claims will be denied unless the physician clearly documents the medical necessity for continued parenteral nutrition and any changes to the therapeutic regimen that are planned, e.g., an increase in the quantity of parenteral nutrients provided.

2. A total caloric daily intake (parenteral, enteral and oral) of 20-35 cal/kg/day is considered sufficient to achieve



or maintain appropriate body weight. The ordering physician must document in the medical record the medical necessity for a caloric intake outside this range in an individual recipient.

3. Parenteral nutrition would usually be noncovered for recipients who do not meet criteria in H.1-3, but will be considered on an individual case basis if detailed documentation is submitted.

4. Recipients covered under criteria in B.1 or 2 must have documentation that adequate small bowel adaptation had not occurred which would permit tube enteral or oral feedings.

5. Recipients covered under B.3 must have documentation of worsening of their underlying condition during attempts to resume oral feedings.

6. The ordering physician must document the medical necessity for protein orders outside of the range of 0.8-1.5 gm/kg/day, dextrose concentration less than 10 percent, or lipid use greater than 15 units of a 20 percent solution or 30 units of a 10 percent solution per month.

7. If the medical necessity for special parenteral formulas is not substantiated, authorization of payment will be denied.

**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 43:1183 (June 2017).

#### **§707. Prior Authorization**

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

**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 43:1184 (June 2017).

#### **§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.

**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 43:1184 (June 2017).

#### **§713. Equipment and Supplies**

A. An infusion pump is used to deliver nutritional requirements intravenously. Infusion pumps are covered for the delivery of parenteral nutrition for those recipients who cannot absorb nutrients by the gastrointestinal tract. Only one pump (ambulatory or stationary) will be covered at any one time. Additional pumps will be denied as not medically necessary.

**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 43:1184 (June 2017).

#### **§715. Reimbursement**

A. The reimbursement rate for parenteral nutrition formula is 80 percent of the Medicare Fee Schedule amount or billed charges, whichever is the lesser amount.

B. The reimbursement rate for parenteral equipment and supplies is 70 percent of the Medicare Fee Schedule amount or billed charges, whichever is the lesser amount. If an item is not available at 70 percent of the Medicare Fee Schedule amount, the flat fee that will be utilized is the lowest cost at which the item has been determined to be widely available by analyzing usual and customary fees charged in the community.

**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).

## **Chapter 9. Methods of Payment**

### **Subchapter A. General Provisions**

#### **§901. Definitions**

*Brand Name*—any registered trade name commonly used to identify a drug.

*Legend Drugs*—drugs which bear the federal legend: “Caution: federal law prohibits dispensing without a prescription.”

*Multiple Source Drug*—a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

*National Average Drug Acquisition Cost (NADAC)*—a national pricing benchmark that is reflective of actual invoice costs that pharmacies pay to acquire prescription and over-the-counter drugs. It is based upon invoice cost data collected from retail community pharmacies and reflects actual drug purchases.

*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*—the lowest price the pharmacy would charge to a particular customer if such customer were paying cash for the identical prescription drug or prescription drug services on the date dispensed.

*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.

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### **§903. Claims Documentation**

A. The manufacturer number, product number, and package number for the drug dispensed shall be listed on all claims. This information shall be taken from the actual package from which the drug is 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. In such instances, the manufacturer number, product number, and package number for the largest package size, as reported in one or more national compendia for the drug shall be listed.

**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 32:1062 (June 2006).

## **Subchapter B. Professional Dispensing Fee**

### **§915. General Provisions**

A. The professional dispensing fee shall be set by the department and reviewed periodically for reasonableness, and when deemed appropriate by the Medicaid Program, may be adjusted considering such factors as fee studies or surveys.

B. Provider participation in the Louisiana cost of dispensing survey shall be mandatory. A provider's failure to cooperate in the survey shall result in his/her removal from participation as a provider of pharmacy services in the Medicaid Program. Any provider removed from

participation shall not be allowed to re-enroll until a professional dispensing fee survey document is properly completed and submitted to the department.

**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, LR 36:1558 (July 2010), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1554 (August 2017).

## **Subchapter C. Estimated Acquisition Cost**

### **§935. Estimated Acquisition Cost Formula**

A. Estimated acquisition cost (EAC) is the national average drug acquisition cost (NADAC) of the drug dispensed. If there is not a NADAC 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).

**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 43:1184 (June 2017), LR 45:571 (April 2019).

## **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.

B. Payment will be made for medications in accordance with the payment procedures for any fee-for-service (FFS) Medicaid eligible person.

C. The pharmacy must be licensed to operate in Louisiana except:

1. as provided for a person residing near the state line; or
2. as provided for a recipient visiting out-of-state.

D. Payment will be made only to providers whose records are subject to audit.

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 43:1184 (June 2017), LR 45:571 (April 2019).

#### **§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 43:1185 (June 2017).

#### **§949. Fee for Service Cost Limits**

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

1. national average drug acquisition cost (NADAC) plus the professional dispensing fee:

a. if no NADAC is available, use the wholesale acquisition cost (WAC) plus the professional dispensing fee; or

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, the term *general public* does not include any person whose prescriptions are paid by third-party payors, including health insurers, governmental entities, and Louisiana Medicaid.

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. NADAC plus the professional dispensing fee:

a. if no NADAC is available, use the WAC plus the professional dispensing fee; or

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, the term *general public* does not include any person whose prescriptions are paid by third-party payors, including health insurers, governmental entities, and Louisiana Medicaid.

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 all of 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.

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.

2. Any practice which precludes the prescriber's handwritten statement shall not be accepted as a valid certification. Such practices include, but are not limited to:

- a. a printed box on the prescription blank that could be checked by the prescriber to indicate brand necessity;
- b. a handwritten statement transferred to a rubber stamp and then stamped on the prescription blank; or
- c. preprinted prescription forms using a facsimile of the prescriber's handwritten statement.

E. Fee for Service 340B Purchased Drugs. The department shall make payments for self-administered 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, unless the covered entity has implemented the Medicaid carve-out option, in which case 340B drugs should not be billed to or reimbursed by Medicaid. 340B contract pharmacies shall not bill 340B stock to Medicaid. Fee-for-service outpatient hospital claims for 340B drugs shall use a cost to charge methodology on the interim cost report and settled during final cost settlement. Federally qualified health center (FQHC) and rural health clinic (RHC) claims for physician administered drugs shall be included in the all-inclusive T1015 encounter rate.

F. Federal Supply Schedule Drugs. Drugs acquired at federal supply schedule (FSS) and at a nominal price shall be reimbursed at actual acquisition cost plus a professional dispensing fee.

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. Medicaid-covered physician-administered drugs shall be reimbursed according to the Louisiana professional services fee schedule. Reimbursement shall be determined utilizing the following methodology, and periodic updates to the rates shall be made in accordance with the approved Louisiana Medicaid State Plan provisions governing physician-administered drugs in a physician office setting.

- 1. Average sales price (ASP) plus 6 percent, for drugs appearing on the Medicare file.
- 2. Reimbursement rates for drugs that do not appear on the Medicare file shall be determined utilizing the following alternative methods:
  - a. the wholesale acquisition cost (WAC) of the drug, if available;

- b. if there is no WAC available, the reimbursement rate will be 100 percent of the provider's current invoice for the dosage administered.

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.

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## 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 provides services to the covered entity's patients, including the service of dispensing the covered entity's 340B drugs, in accordance with Health Resources and Services Administration (HRSA) guidelines (75 FR 10272, March 5, 2010). 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.

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

*Medicaid Carve-Out*—a billing mechanism available to covered entities that implements the 340B requirement protecting manufacturers from giving a 340B discount and paying a Medicaid rebate on the same drug. If a covered entity elects to implement the Medicaid carve-out option, the covered entity only purchases through the 340B Program covered drugs dispensed to non-Medicaid patients; drugs

dispensed to Medicaid patients are purchased outside the 340B Program.

*Patient*—an individual eligible to receive 340B-discounted drugs from a covered entity by virtue of being the covered entity's patient as defined in HRSA's 1996 patient definition guideline (61 FR 55156, October 24, 1996).

*Professional Dispensing Fee*—the fee paid by Medicaid for the professional services provided by a pharmacist when dispensing a prescription. Per legislative mandate, the \$0.10 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 43:1186 (June 2017), LR 43:1555 (August 2017), LR 45:572 (April 2019).

### **§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 43:1186 (June 2017).

## **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..

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), repealed LR 33:101 (January 2007), amended LR 34:881 (May 2008), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1186 (June 2017).

## **Subchapter G. Reserved.**

## **Subchapter H. Vaccines**

### **§991. Vaccine Administration Fees**

A. Effective for dates of service on and after October 10, 2009, the reimbursement to pharmacies for immunization administration (intramuscular or intranasal) performed by qualified pharmacists, is a maximum of \$15.22. This fee includes counseling, when performed.

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, LR 36:1783 (August 2010), amended LR 40:82 (January 2014), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1555 (August 2017).

### **§993. Vaccine Reimbursement**

A. Effective for dates of service on or after January 1, 2011, the influenza vaccine for recipients aged 19 and over shall be reimbursed at 90 percent of the 2009 Louisiana Medicare average sales price (ASP) allowable or billed charges, whichever is the lesser amount.

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, LR 40:82 (January 2014).

## **Chapter 11. State Supplemental Rebate Agreement Program**

### **§1101. General Provisions**

A. The Centers for Medicare and Medicaid Services approved LDH to enter into state supplemental rebate agreements with pharmaceutical manufacturer(s). LDH may enter into an agreement with a pharmaceutical manufacturer to obtain a rebate(s) in addition to federal rebates pursuant to 42 U.S.C. 1396r. Participation by a pharmaceutical manufacturer in a state supplemental rebate agreement with the department is voluntary.

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, Bureau of Health Services Financing, LR 43:966 (May 2017), amended LR 45:909 (July 2019).