Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XXIX. Pharmacy

Chapter 1. General Provisions

§101-103. Reserved.

§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 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. The formulary is managed through the use of Federal Upper Limits (FUL) and the Louisiana Maximum Allowable Costs (LMAC) limitations. Federal Upper Limits and Louisiana Maximum Allowable Costs limitations provide for dispensing of multiple source drugs at established limitations unless the prescribing physician 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 Price (AWP) discounting, the Louisiana Maximum Allowable Costs (LMAC) limitations and compliance with Federal Upper Limits (FUL) regulations, and the establishment of the maximum allowable overhead costs, drug rebates and copayments.

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. 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 Program which provides for on-going review processes for misutilization, abuse and fraud, and audits of the providers of the Pharmacy Program.

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 eight therapeutic modules in accordance with the standards of the National Council of Prescription Drug Plan. 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 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 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. 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. 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.

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.

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

7. Physicians 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 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, 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)

§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 each pharmacy claim form for reimbursement of prescription drugs 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 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 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. 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 Section 1927(d)(2) of the Social Security Act, the following drugs are excluded from program coverage:

1. experimental drugs;

2. anorexics;

3. cough and cold preparations;

4. cosmetic drugs;

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; and

10. DESI Drugs (see Subsection E below).

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 identical, 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).

§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 to 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).

§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 requirement.

a. services furnished to individuals under 21 years of age;

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;

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

d. emergency services provided in a hospital, clinic, physician office or other facility equipped to furnish emergency care;

e. family planning services and supplies.

B. 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).

§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 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 description is 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-9-CM, or its successor, diagnosis code is required for each prescription in excess of four for that 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. 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).

§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 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 a narcotic 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 a cosmetic drug, anorexic cough and cold preparation, minor tranquilizer, or 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 which are generally labeled: ACaution - limited by federal law to investigational use,≅ 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 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 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 will provide coverage information on any specific drug. Providers should contact the fiscal intermediary's provider 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 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).

§117. Time Limits

A. Filling Prescriptions. Prescriptions for drugs other than a controlled substance shall expire one year after the date prescribed by a physician or other service practitioner covered under the Medicaid Program and shall be refilled not more than 11 times in one year. A prescription for a controlled dangerous substance listed in Schedule II, 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. 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. 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).

§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_{12} 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 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).

§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

§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).

§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;

2. conduct a telephone interview 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. 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).

§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. 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).

§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 DHH 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 DHH'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).

§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. 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).

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 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 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).

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.

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 luoroscopy. 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).

§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.

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).

§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.

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).

§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.

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.

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).

§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.

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).

§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.

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.

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

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).

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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

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Subchapter C. Average Wholesale Price

§935. Estimated Acquisition Cost Formula

A. *Estimated Acquisition Cost (EAC)* is the modified average wholesale price 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.

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.

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).

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 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.

B. Payment will be made for medications in accordance with the payment procedures for any eligible person who has identified himself to the provider by presenting his identification card which shows his eligibility. State office advises participating pharmacists regarding payable medication.

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 licensed physician or dentist.

F. Payments will be made only for the drugs covered under the Medical Assistance Program’s Pharmacy Program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

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§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 suboffice 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 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).

§949. Cost Limits

A. Federal Upper Limits for Multiple Source Drugs

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.

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

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.

B. Louisiana Maximum Allowable Cost (LMAC) Limits

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.

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.

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.

C. Lower of Reimbursement 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;

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

3. any applicable Federal Upper Limit for Multiple Source Drugs plus the agency's established dispensing fee; or

4. any applicable Louisiana Maximum Allowable Cost limit plus the agency's established dispensing fee.

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 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;

c. preprinted prescription forms using a facsimile of the prescriber's handwritten statement.

E. Other Drug Cost Limits. The agency shall make payments for drugs other than multiple source drugs and drugs subject to APhysician Certifications≅ based on the lower of:

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≅.

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, 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.

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.

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).

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).

§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 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.

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.

C. Dispensing Fees. The covered entity shall 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.

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).

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 plus 10 percent and the 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.

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).