NOTICE OF INTENT

Department of Health
Bureau of Health Services Financing

Pharmacy Benefits Management Program
Dispense as Written Electronic Prescribing
(LAC 50:XXIX.Chapters 1,5,7,9 and 11)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XXIX.Chapters 1,2,7,9 and 11 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health, Bureau of Health Services Financing currently only allows handwritten “brand necessary” notation of the medical necessity of brand drugs by prescribing providers in the Pharmacy Benefits Management Program. The department has determined that electronic prescriptions are safer in preventing prescription drug errors from the misreading of handwriting, eliminate the ability to alter or manipulate the prescription, and speed up the workflow process. The department now proposes to amend the provisions governing the Pharmacy Benefits Management Program in order to allow notation of the medical necessity of brand drugs using electronic prescriptions, to allow the state to pursue outcomes-based agreements with manufacturers, and to align the provisions with the current Medicaid State Plan.
Title 50
PUBLIC HEALTH MEDICAL ASSISTANCE
Part XXIX. Pharmacy

Chapter 1. General Provisions

§107. Prior Authorization

A. - C.3. ...

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

1. experimental drugs and investigational drugs select agents when used for anorexia, weight loss, or weight gain, except Orlistat (Xenical®);

2. drugs select agents when used to treat weight loss promote fertility, except Orlistat vaginal progesterone when used for high-risk pregnancy to prevent premature births;

3. select agents when used for symptomatic relief of cough and cold preparations, except some prescription antihistamine and antihistamine/decongestant combination products;

4. cosmetic drugs, except Isotretinoin select prescription vitamins and mineral products, except:
   a. prenatal vitamins;
   b. fluoride preparations;
   c. vitamin A injection;
d. vitamin B injection;  

e. vitamin D (prescription only);  
f. vitamin K (prescription only);  
g. vitamin B12 injection;  
h. folic acid (prescription only);  
i. niacin (prescription only);  
j. vitamin B6 injection;  
k. vitamin B1 injection;  
l. multivitamin (prescription only);  
m. magnesium injections;  
n. calcium injection; and  
o. urinary PH modifiers (phosphorus, specifically K Phos Neutral and Phospha Neutral);  

5. compounded prescriptions (mixtures of two or more ingredients—the individual select nonprescription drugs will continue to be reimbursed) except OTC antihistamines and antihistamine/decongestant combinations and polyethylene glycol 3350 (Miralax®);  

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).

Repealed.

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. Otherwise Restricted Drugs

1. The state will cover agents when used for cosmetic purposes or hair growth only when the state has determined that use to be medically necessary.

2. Select drugs for erectile dysfunction, except when used for the treatment of conditions, or indications approved by the FDA, other than erectile dysfunction.


HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health
§111. Copayment

A. - A.1. ...

* * *

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

   a. - d. ...

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

   a. individuals under the age of 21;
   b. individuals residing in a long-term care facility;
   c. individuals receiving hospice care;
   d. Native Americans and Alaskan Eskimos;
   e. women whose basis for Medicaid eligibility is breast or cervical cancer; and
   f. home and community-based services waiver recipients.
B. In accordance with federal regulations, the following population groups are exempt from copayment requirements:

1. **Individuals under the age of 21.** 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. **Individuals residing in a long-term care facility.** Providers shall not waive the recipient copayment liability.

3. **Individuals receiving hospice care.** Departmental monitoring and auditing will be conducted to determine provider compliance.

4. **Native Americans and Alaskan Eskimos.** Violators of this Section maybe subject to a penalty, including but not limited to, termination from the Medicaid Program.

5. **Women whose basis for Medicaid eligibility is breast or cervical cancer, and household do not exceed an aggregate limit of 5 percent of the family’s income applied on a monthly basis.**
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), LR 46:
§115. Drug Coverage Limits

A. - 5.c. ...

   6. The prescribed drug is not a cosmetic drug, anorexic, cough and cold preparation, or selected nonprescription drug an excluded or otherwise restricted drug.

   7. ...

   8. The prescribed drug is not an immunosuppresant drug prescribed and billed to Medicare within one year from the date of the transplant for a Title XIX transplant 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. - 2. ...

C. Erectile Dysfunction Drugs. Prescription drugs for the treatment of sexual or erectile dysfunction shall not be covered or reimbursed under the Medicaid Program. Repealed.
AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1055 (June 2006), LR 32:2083 (November 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1182 (June 2017), LR 46:

§119. Maximum Quantity

A. ...

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 after the initial fill.

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, B12 injection;
   b. Folic Acid; and

C. ...

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

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1056 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1182 (June 2017), LR 46:

Chapter 5. Narcotics and Controlled Substances

$501. Schedule II Narcotic Analgesic Prescriptions

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

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1058 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1183 (June 2017), LR 46:

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. Repealed.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1058 (June 2006), repealed LR 46:

§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. Repealed.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1058 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1183 (June 2017), repealed LR 46:

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

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1060 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017), repealed LR 46:

§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. Repealed.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1061 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017), repealed LR 46:

§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. **Repealed.**

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

**HISTORICAL NOTE:** Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1061 (June 2006), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017), repealed LR 46:

§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. Repealed.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1061 (June 2006), repealed LR 46: Chapter 9. Methods of Payment

Subchapter D. Maximum Allowable Costs

§949. Fee for Service Cost Limits

A. - C.3.c. ...

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 in his own handwriting or via an electronic prescription. Such certification may shall be written directly on the prescription, or on a separate sheet which is dated and attached to the prescription, or submitted electronically. A standard phrase in the prescriber's handwriting, such as "brand necessary" indicating the medical necessity of the brand 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.

Section 2. – 2.c. Repealed.

E. - K. ...

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


Chapter 11. State Supplemental Rebate – Value-based Agreement Programs

Subchapter E. 340B Program
§1101. General Provisions

A. ... 

B. LDH may enter into an agreement with a pharmaceutical manufacturer for outcomes-based contracts. Participation by a pharmaceutical manufacturer in an outcomes-based 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), LR 46: 

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability and autonomy as described in R.S. 49:972.

Poverty Impact Statement
In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

**Small Business Analysis**

In compliance with Act 820 of the 2008 Regular Session of the Louisiana Legislature, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule will have no impact on small businesses, as described in R.S. 49:965.2 et seq.

**Provider Impact Statement**

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, no direct or indirect cost to the provider to provide the same level of service, and will have no impact on the provider’s ability to provide the same level of service as described in HCR 170.

**Public Comments**
Interested persons may submit written comments to Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on November 29, 2019.

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on November 12, 2019. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on November 27, 2019 in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after November 12, 2019. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage, which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing
attendees when the parking ticket is presented to LDH staff at the hearing.

Rebekah E. Gee MD, MPH

Secretary