

Table of Contents

State/Territory Name: Louisiana

State Plan Amendment (SPA) #: 17-0008 PHARM

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form
- 3) Approved Page

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

September 22, 2017

Jen Steele, Medicaid Director
State of Louisiana
Department of Health
628 North 4th Street
P.O. Box 91030
Baton Rouge, LA 70821-9030

Dear Ms. Steele:

We have reviewed Louisiana's State Plan Amendment (SPA) 17-0008 received in the Dallas Regional Office on June 27, 2017. This SPA proposes to bring Louisiana into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC), such as the provisions in 42 CFR 447.518(a). In addition, the SPA addresses coverage policies of covered outpatient drugs.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 17-0008 is approved with an effective date of April 20, 2017. A copy of the revised signed CMS-179 form, as well as the pages approved for incorporation into Louisiana's state plan will be forwarded by the Dallas Regional Office.

If you have any questions regarding this amendment, please contact Terry Simananda at (410) 786-8144 or terry.simananda@cms.hhs.gov.

Sincerely,

/s/

Meagan T. Khau
Deputy Director
Division of Pharmacy

CC: Bill Brooks, ARA, CMS, Dallas Regional Office
Cheryl Rupley, CMS, Dallas Regional Office

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Dallas Regional Office
1301 Young Street, Suite 833
Dallas, Texas 75202



DIVISION OF MEDICAID & CHILDREN'S HEALTH - REGION VI

September 22, 2017

Ms. Jen Steele, State Medicaid Director
Department of Health
628 North 4th St.
Post Office Box 91030
Baton Rouge, LA 70821-9030

Attention: Karen Barnes

Dear Ms. Steele:

This letter is being sent as a companion to our approval of Louisiana State Plan Amendment (SPA) 17-0008. This SPA proposes to bring Louisiana into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC), such as the provisions in 42 Code of Federal Regulations (CFR) 447.518(a). In addition, the SPA addresses coverage policies of covered outpatient drugs. Our review included an analysis of the entire content of the submitted pages, including the reimbursement methodology for physician administered drugs.

Attachment 4.19-B, Item 12.a, Page 3, of the State plan indicates that the state reimburses Physician Administered Drugs, Physician Office Setting, based on the Louisiana professional services fee schedule that is set at 90 percent of the Louisiana Medicare Region 99 rate at the time the appropriate drug code is added or billed charges, whichever is the lesser amount. Based on our review and communications with your staff, it appears that the state is freezing prices of all physician administered drugs once added to Louisiana's program payment file. CMS would like a better understanding as to how the state will monitor its program to ensure that the reimbursement rates for physician administered drugs available to Louisiana physician practitioner providers are current; along with how often the state update these rates.

In accordance with section 1902(a)(30)(A) of the Social Security Act (the Act), which in part requires, that states have methods and procedures to assure payment rates are consistent with efficiency, economy, and quality of care, please make amendments to the State plan page(s) to reflect the current reimbursement rate for physician administered drugs. Additionally, please explain how often these rates are updated.

Please respond to this letter within 90 days of its receipt with a corrective action plan describing how you will resolve the issues identified above. During the 90-day period, we are happy to provide any technical assistance that you need. State plans that are not in compliance with section 1902(a) (30) (A) of the Act are grounds for initiating a formal compliance process.

If you have any questions regarding this letter, please contact Cheryl Rupley at 214-767-6278 by phone or by email at Cheryl.rupley@cms.hhs.gov.

Sincerely,



Bill Brooks
Associate Regional Administrator
Division of Medicaid & Children's Health

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	1. TRANSMITTAL NUMBER: 17-0008	2. STATE Louisiana
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
FOR: HEALTH CARE FINANCING ADMINISTRATION	4. PROPOSED EFFECTIVE DATE April 20, 2017	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES		

5. TYPE OF PLAN MATERIAL (Check One):
G NEW STATE PLAN G AMENDMENT TO BE CONSIDERED AS NEW PLAN AMENDMENT
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)

6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR 440.120 42 CFR Part 447	7. FEDERAL BUDGET IMPACT: a. FFY <u>2017</u> \$ 50,515 b. FFY <u>2018</u> \$122,252
---	---

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A, Item 12a, Pages 1, 2, 3, 3a, and 4 Attachment 3.1-A, Item 12a, Pages 4a Attachment 3.1-A, Item 12a, Page 5 Attachment 3.1-A, Item 12a, Page 6 Attachment 4.19-B, Item 12a, Pages 1, 2, 3, 4, 4a, 5 and 6 Attachment 4.19-B, Item 12a, Pages 7, 8, 9, 10, 11, 12 and 13 Attachment 3.1-A, Item 12a, Page 3a	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Same (TN 14-11) Same (TN 05-40) Remove Same (TN 13-44) Remove Remove page Same (TN 02-06) Same (TN 12-55) Remove pages 4, 4a, 5 & 6 Remove pages *see Appendix to Form 179 Same (TN 14-11) Pending SPA LA TN 17-0018-Remove
--	---

10. SUBJECT OF AMENDMENT: **The SPA proposes to revise the provisions governing the Pharmacy Benefits Management program in order to clarify requirements regarding 340B-covered entities and to revise the reimbursement methodology to include federal upper limits (FUL), new copayment exemptions and over-the-counter medications added for expansion benefits pursuant to CMS' recently released regulations.**

11. GOVERNOR'S REVIEW (Check One):
 GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED:
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED **The Governor does not review state plan material.**
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL: 	16. RETURN TO: Jen Steele, Medicaid Director State of Louisiana Department of Health 628 North 4th Street P.O. Box 91030 Baton Rouge, LA 70821-9030
13. TYPED NAME: Rebekah E. Gee MD, MPH	
14. TITLE: Secretary	
15. DATE SUBMITTED: June 29, 2017	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: June 29, 2017	18. DATE APPROVED: September 22, 2017
-------------------------------------	--

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: April 20, 2017	20. SIGNATURE: 
21. TYPED NAME: Bill Brooks	22. TITLE: Associate Regional Administrator Division of Medicaid & Children's Health

23. REMARKS: **Please see pen and ink change to boxes 6, 8 and 9.**

STATE OF LOUISIANA

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED
LIMITATIONS ON THE AMOUNT, DURATION, AND SCOPE OF CERTAIN ITEMS OF PROVIDED
MEDICAL AND REMEDICAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

<u>CITATION</u>	Medical and Remedial	<u>Prescribed drugs, and Prosthetic Devices; and Eyeglasses</u>
42 CFR	Care and Services	<u>Prescribed by a Physician Skilled in Diseases of the Eye or by</u>
440.120	Item 12.a.	<u>an Optometrist</u>

Item 12.a. Prescribed drugs are limited as follows:

Vendor payments are made for prescribed medications and/or supplies. The medications must be prescribed by a practitioner authorized to prescribe under State law. The National Drug Code (NDC) must be shown on each pharmaceutical claim form for reimbursement of prescription drugs subject to rebates from manufacturers as prescribed by mandatory federal law and regulations.

A. Drugs for Full Benefit Dual Eligible

Effective January 1, 2006, Louisiana Medicaid will not reimburse any drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B, which would entitle the dual eligible individual to receive drug benefits under the Medicare Prescription Drug Benefit, Part D. The only drugs covered for the full-benefit dual eligible by Louisiana Medicaid are those subject to restriction under Section 1927(d) (2) of the Social Security Act.

B. Medicaid Coverage of Drugs Restricted Under Section 1927(d) (2) of the Social Security Act

The Medicaid Program will provide coverage for the following drugs which may be excluded, or otherwise restricted, under the provisions of Section 1927(d)(2) of the Social Security Act. The Medicaid agency will not pay when Medicare Part B or Part D plans reimburse for these drugs.

Excluded Drugs:

- Select agents when used for anorexia, weight loss, or weight gain
Xenical only
- Select agents when used to promote fertility
Vaginal progesterone when used for high-risk pregnancy to prevent premature births
- Select agents when used for symptomatic relief of cough and colds
Prescription Antihistamine and Antihistamine/Decongestant Combination Products

State: Louisiana
Date Received: 6-29-17
Date Approved: 9-22-17
Date Effective: 4-20-17
Transmittal Number: 17-0008

STATE OF LOUISIANA

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED
LIMITATIONS ON THE AMOUNT, DURATION, AND SCOPE OF CERTAIN ITEMS OF PROVIDED
MEDICAL AND REMEDICAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

- Select prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

Vitamin A Injection

Vitamin B Injection

Vitamin D (prescription only)

Vitamin K (prescription only)

Vitamin B12 Injection

Folic Acid (prescription only)

Niacin (prescription only)

Vitamin B6 Injection

Vitamin B1 Injection

Multivitamin (prescription only)

Magnesium Injection

Calcium Injection

Urinary PH modifiers (Phosphorous, specifically K Phos Neutral and Phospha Neutral)

- Select nonprescription drugs
OTC antihistamines and antihistamine/decongestant combinations
Miralax

- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

Otherwise Restricted Drugs:

- 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.
- Select drugs for erectile dysfunction
When used for the treatment of conditions, or indications approved by the FDA, other than erectile dysfunction.

State: Louisiana
Date Received: 6-29-17
Date Approved: 9-22-17
Date Effective: 4-20-17
Transmittal Number: 17-0008

STATE OF LOUISIANA

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED
LIMITATIONS ON THE AMOUNT, DURATION AND SCOPE OF CERTAIN ITEMS OF
PROVIDED MEDICAL AND REMEDIAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

C. Monthly Prescription Limit

1. The program will pay for a maximum of four prescriptions per calendar month for Medicaid recipients.
2. The following federally mandated recipient groups are exempt from the four prescriptions per calendar month limitations:
 - a. Persons under 21 years of age;
 - b. Persons who are residents of long-term care institutions, such as nursing facilities and intermediate care facilities for individuals with intellectual disabilities; and
 - c. Pregnant women.
3. The four prescriptions per month limit can be exceeded when the prescriber determines an additional prescription is medically necessary.
4. Pharmacists and prescribers are required to maintain documentation to support the override of a prescription limitation.

D. Supplemental Drug Rebates

1. As authorized by LA R.S. 46:153.3 (B)(2)(a) the State Supplemental Drug Rebate program is effective April 1, 2002.
2. The state negotiates supplemental rebates from manufacturers that are in addition to those mandated by Title XIX of the Social Security Act.
3. The Department is in compliance with Section 1927 of the Social Security Act. Based on the requirements for Section 1927, the Department has the following policies for drug rebate agreements:
 - a. The drug file permits coverage of participating manufacturers' drugs;
 - b. The program is in compliance with reporting for state utilization information and restrictions to coverage;
 - c. Rebate agreements between the Department and a drug manufacturer that are separate from the drug rebate agreements of Section 1927 are approved by the Centers for Medicare and Medicaid Services. The Department reports supplemental rebates from separate agreements to the Secretary for Health and Human Services. The Department will remit the federal portion of any state supplemental rebates collected.

State: Louisiana
Date Received: 6-29-17
Date Approved: 9-22-17
Date Effective: 4-20-17
Transmittal Number: 17-0008

STATE OF LOUISIANA

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED
LIMITATIONS ON THE AMOUNT, DURATION AND SCOPE OF CERTAIN ITEMS OF
PROVIDED MEDICAL AND REMEDIAL CARE AND SERVICES DESCRIBED AS FOLLOWS:

- d. Manufacturers are allowed to audit utilization data;
 - e. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification; an
 - f. The Department will utilize the same processes to resolve State Supplemental rebate issues as it uses to resolve federal rebate disputes and as outlined in CMS' *Best Practices Guide for Dispute Resolution Under the Medicaid Drug Rebate Program*.
- 4. The Department is also in compliance with state regulations relative to the confidentiality of supplemental rebate information contained in the records of the Department and its agents.
 - 5. A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on April 8, 2002 and entitled "Supplemental Rebate Agreement", was previously authorized by CMS on April 25, 2002.
 - 6. CMS has authorized the state of Louisiana to enter into *The Optimal PDL Solution (TOP\$)*. This Supplemental Drug Rebate Agreement was submitted to CMS on November 5, 2013, and has been authorized by CMS effective October 1, 2013.

State: Louisiana
Date Received: 6-29-17
Date Approved: 9-22-17
Date Effective: 4-20-17
Transmittal Number: 17-0008

TN 17-0008 Approval Date 9-22-2017 Effective Date 4-20-2017
Supersedes
TN 14-11

STATE OF LOUISIANA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICES

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES – OTHER TYPES OF CARE OR SERVICES LISTED IN SECTION 1902(a) OF THE ACT THAT ARE INCLUDED IN THE PROGRAM UNDER THE PLAN ARE DESCRIBED AS FOLLOWS:

<u>CITATION</u>	Medical and Remedial	<u>Prescription drugs, dentures, and prosthetic devices and Eyeglasses</u>
42 CFR	Care and Services	<u>Prescribed by a Physician Skilled in Diseases of the Eye, or by an</u>
447	Item 12.a.	<u>Optometrist.</u>
Subpart D		

Prescribed drugs are reimbursed as follows:

I. PROFESSIONAL DISPENSING FEE

The Department has established a professional dispensing fee which shall be reviewed periodically for reasonableness, and when deemed appropriate by Louisiana Medicaid, may be adjusted considering such factors as fee studies or surveys.

The pharmacy provider will be reimbursed at the appropriate ingredient cost plus the maximum allowable professional dispensing fee or the usual and customary charge, whichever is less

Professional Dispensing Fee Amount

1. The professional dispensing fee for drugs dispensed to Louisiana Medicaid enrollees will be \$10.41 per prescription. The provider fee will be reimbursed separately, per legislative mandate.
2. The professional dispensing fee for drugs dispensed to Louisiana Medicaid enrollees and obtained through the Public Health Service 340B Program will be \$10.41 per prescription. The provider fee will be reimbursed separately, per legislative mandate.

II. PHARMACY REIMBURSEMENT METHODOLOGY

Prescription drugs covered by Louisiana Medicaid shall be reimbursed according to the following:

Brand Name Drugs

Payment for single source drugs (brand name drugs) shall be based on the lower of:

1. Louisiana Average acquisition cost (AAC) plus a professional dispensing fee:
 - a. If no AAC is available, use the wholesale acquisition cost (WAC) plus the professional dispensing fee; or
2. the provider's usual and customary charges to the general public

State: Louisiana
Date Received: 6-29-17
Date Approved: 9-22-17
Date Effective: 4-20-17
Transmittal Number: 17-0008

STATE OF LOUISIANA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICES

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - OTHER TYPES OF CARE OR SERVICE LISTED IN SECTION 1902 (A) OF THE ACT THAT ARE INCLUDED IN THE PROGRAM UNDER THE PLAN ARE DESCRIBED AS FOLLOWS:

Generic Drugs

Payment for multiple source drugs (generic drugs), other than drugs subject to “physician certifications”, shall be based on the lower of:

1. The Louisiana AAC plus the professional dispensing fee:
 - a. If the Louisiana AAC is not available, use the WAC plus the professional dispensing fee;
2. Federal upper payment limits plus the professional dispensing fee; or
3. The provider’s usual and customary charges to the general public.

340B Purchased Drugs

Payment for self-administered drugs that are purchased by a covered entity through the 340B program shall be made at the 340B acquisition cost, which can be no more than the 340B ceiling price, plus the professional dispensing fee.

Drugs purchased outside of the 340B program, will be reimbursed using the methodology described in Section II, plus a professional dispensing fee.

Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered.

Federal Supply Schedule Drugs

Drugs acquired at the Federal Supply Schedule (FSS) will be reimbursed at the FSS actual acquisition cost, plus the professional dispensing fee

Nominal Price Drugs

Drugs acquired at Nominal Price (outside of 340B or FSS) will be reimbursed at their actual acquisition cost, plus the professional dispensing fee.

Indian Health Service All-Inclusive Encounter Rate

Pharmacy services provided by the Indian Health Service (IHS) or tribal facilities shall be included in the encounter rate.

Mail Order, Long-Term Care and Specialty Pharmacy

Drugs dispensed by mail order, long-term care (LTC) and/or specialty pharmacies (drugs not distributed by a retail community pharmacy) will be reimbursed using the brand/generic drug reimbursement methodology, plus a professional dispensing fee.

State: Louisiana
Date Received: 6-29-17
Date Approved: 9-22-17
Date Effective: 4-20-17
Transmittal Number: 17-0008

STATE OF LOUISIANA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICES

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - OTHER TYPES OF CARE OR SERVICE LISTED IN SECTION 1902 (A) OF THE ACT THAT ARE INCLUDED IN THE PROGRAM UNDER THE PLAN ARE DESCRIBED AS FOLLOWS:

Physician-Administered Drugs

Physician Office Setting

Reimbursement is based on the Louisiana professional services fee schedule that is set at 90 percent of the Louisiana Medicare Region 99 rate at the time the appropriate drug code is added or billed charges, whichever is the lesser amount.

Outpatient Hospital Setting

Interim payment rate for claims is the hospital specific cost to charge ratio. Final payment is made during the cost report settlement process at the percentage of allowable costs specified in our approved state plan for the type of hospital and applicable dates of service. This applies to both 340B and regular drug stock in this setting.

340B Physician Administered Drugs

Reimbursement is encompassed in the all-inclusive encounter rate for Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs).

Clotting Factor

Pharmacy claims for clotting factor will be reimbursed using the brand/generic drug reimbursement methodology plus a professional dispensing fee.

Investigational or Experimental Drugs

Investigational or experimental drugs shall not be reimbursed by Louisiana Medicaid.

State: Louisiana
Date Received: 6-29-17
Date Approved: 9-22-17
Date Effective: 4-20-17
Transmittal Number: 17-0008

TN 17-0008 Approval Date 9-22-2017 Effective Date 4-20-2017

Supersedes

TN 12-55