



Division of Medicaid & Children's Health, Region VI

March 15, 2011

Our Reference: SPA LA 10-79

Mr. Don Gregory, State Medicaid Director
Department of Health and Hospitals
Bienville Building
628 North 4th Street
Post Office Box 91030
Baton Rouge, LA 70821-9030

Dear Mr. Gregory:

This letter is being sent as a companion to our approval to Louisiana State Plan Amendment 10-79. During our review of that SPA, the Centers for Medicare & Medicaid Services (CMS) performed an analysis of the section in the plan associated with over the counter (OTC) drugs. Based on that review, it was determined that certain areas in the coverage section were not consistent with current guidance and regulations at section 1927(d)(2) and (k)(2) of the Social Security Act (the Act) regarding the definition of covered outpatient drug.

In order to ensure compliance with current regulations and policy related to the above provisions, the State is responsible for the following:

1. Other Items Covered as Pharmacy Services which are not Covered Under 1927(d)(2) of the Act).
On Page 3c. Item F. - the current State plan specifies various Over-the-Counter (OTC) preparations, supplies, items and agents, etc. that do not meet the definition of a covered outpatient drug in accordance with section 1927(k) of the Act. Please remove the following items from the Pharmacy section of the State plan:

OTC Vitamin D preparations; OTC Vitamin E preparations; OTC Niacin preparations; OTC Calcium Replacement Agents; OTC Magnesium Replacement Agents; OTC Phosphate Replacement Agents; OTC Iron Replacement Agents; Normal Saline and Heparin flushes; Diabetic Supplies; Family Planning Agents

While these products are not eligible for Medicaid coverage under the Medicaid Drug Rebate program, they may be eligible for coverage under other Medicaid benefit categories such as home health services or Early and Periodic, Screening, Diagnosis and Treatment (EPSDT) Program, depending on whether such coverage is consistent with the State plan.

It is allowable for the State to specify “contraceptive jellies and foams” instead of “Family Planning Items” in the Pharmacy section of the State plan. Please revise this section of the State plan.

The State has 90 days from the date of this letter to address the issues described above. Within that period the State may submit SPAs to address the inconsistencies or submit a corrective action plan describing in detail how the State will resolve the issues identified above in a timely manner. Failure to respond will result in the initiation of a formal compliance process. During the 90 days, CMS will provide any required technical assistance.

If you have any questions about this request, please contact Ford Blunt of my staff at either 214-767-6381 or by E-mail at ford.blunt@cms.hhs.gov.

Sincerely,



Bill Brooks
Associate Regional Administrator

Cc: Allyson Lamy

Marks, Marsha L. (CMS/SC)

From: Marks, Marsha L. (CMS/SC)
Sent: Thursday, March 17, 2011 8:54 AM
To: CMS SPA; CMS CMSO_508_SPA
Cc: Blunt, Ford J. (CMS/SC); Jackson, Teresa K. (CMS/CMCHO); Carter, Demetria (CMS/SC); Monroe, Monique S. (CMS/CMCHO); Cieslicki, Mary E. (CMS/CMCS)
Subject: Final Approval Pkg for LA 10-79
Attachments: Final Approval Letter for LA 10-79.pdf; TX1079COMPANION.doc

See Attached.

State: Louisiana

Brief Description: The plan amendment proposes reimbursement to pharmacies for immunizations administration at \$15.22 for subcutaneous or intramuscular injection at \$10.80 for nasal/oral administration or billed charges, whichever is the lesser amount. No Tribal Consultation was required with this SPA.

Approval Date: 9 March, 2011

Effective Date: 1 January, 2011

Marsha Marks // Dept of Health & Human Services // Centers for Medicare & Medicaid Services // Dallas Regional Office // Division of Medicaid & Children's Health // Dallas Texas 75202 // 214-767-6280 // Fax 214-767-0322 // marsha.marks@cms.hhs.gov

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM
STATE OF LOUISIANA

Attachment 4.19-B
Item 6, Page 11

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICES

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -- OTHER TYPES OF CARE OR SERVICES LISTED IN SECTION 1905(A) OF THE ACT THAT ARE INCLUDED IN THE PROGRAM UNDER THE PLAN ARE DESCRIBED AS FOLLOWS:

CITATION Medical and Remedial Pharmacists
42 CFR Care and Services
447.201 Item 6.d.

Medication Administration

Reimbursement Methodology:

Effective for dates of service on or after January 1, 2011, reimbursement to qualified pharmacists for immunization administration is \$15.22 for subcutaneous or intramuscular injection, \$10.80 for nasal/oral administration, or billed charges, whichever is the lesser amount. This fee includes counseling, when performed.

Reimbursement for a dispensing fee will not be allowed when an administration fee is paid.

SUPERSEDES: TN- 09-50

STATE <u>Louisiana</u>	A
DATE REC'D <u>12-20-10</u>	
DATE APP'D <u>3-9-11</u>	
DATE EFF <u>1-1-11</u>	
HCFA 179 <u>10-79</u>	

TN# 10-79 Approval Date 3-9-11 Effective Date 1-1-11
Supersedes
TN# 09-50

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICES

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -- OTHER TYPES OF CARE OR SERVICES LISTED IN SECTION 1905(A) OF THE ACT THAT ARE INCLUDED IN THE PROGRAM UNDER THE PLAN ARE DESCRIBED AS FOLLOWS:

CITATION Medical and Remedial
42 CFR Care and Services
447 Subpart I Item 12.a.(Continued)

E. Physician Certifications

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 beneficiary. Such certification shall be written directly on the prescription or on a separate sheet which is attached to the prescription. The wording of the certification should testify to the medical necessity of the brand name drug by stating either "brand medically necessary" or "brand necessary".

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

1. A printed box on the prescription blank that could be checked by the prescriber to indicate brand necessity.
2. A handwritten statement transferred to a rubber stamp and then stamped on the prescription blank.
3. Preprinted prescription forms using a facsimile of the prescriber's handwritten statement.

F. Effective for dates of service on and after January 1, 2011, influenza vaccines shall be reimbursed at the following rates or billed charges, whichever is the lesser amount:

<u>Vaccine</u>	<u>Vaccine Reimbursement</u>
Influenza Vaccine, Preservative Free, IM	\$17.37
Influenza Vaccine, IM	\$13.22
Influenza Vaccine, Intranasal	\$22.03

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IV. GENERAL REQUIREMENTS APPLICABLE TO ALL PRESCRIPTIONS

- 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 such cases, the maximum quantity payable shall be filled.
- B. When maintenance drugs are prescribed and dispensed for chronic illness, they shall be in quantities sufficient to effect economy in dispensing and yet be medically sound. Listed below are drugs that Medicaid considers maintenance type drugs and which should be prescribed and dispensed in a month's supply:

TN# 10-79 Approval Date 3-9-11 Effective Date 1-1-11

Supersedes

TN# 05-11

SUPERSEDES: TN- 05-11

AMLUNT, 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:

CITATION Medical and
42 CFR Remedial Care and
440.60 Services Item 6.d.

5. Pharmacists

Medication Administration

The Department shall provide coverage for administration of the influenza vaccine by a qualified pharmacist when:

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

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AMLUNT, 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:

E. Other Drugs not Covered.

The Louisiana Medicaid program excludes the following drug products from coverage to all Medicaid recipients including the full benefits dual eligibles:

1. Experimental Drugs.
2. Compounded prescriptions (mixtures of two or more ingredients; the individual drugs will continue to be reimbursed).
3. Medications which are included in the reimbursement to a facility, i.e. hospitals, skilled nursing facility for recipients receiving benefits under Part A of Title XVIII, mental hospitals, or some other nursing facilities.
4. Vaccines covered in other programs, except influenza vaccines.
5. DESI Drugs. Those drugs 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 "less than effective" or "identical, related, or similar drugs" which are identified as DESI ineffective drugs shall be excluded from coverage.

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F. Other Items Covered as Pharmacy Services which are not Covered Under 1927(d)(2) of the Social Security Act

The Louisiana Medicaid agency provides coverage for the following items which are not covered under 1927(d)(2) of the Social Security Act to all Medicaid recipients, including full benefit dual eligibles. When Medicare Part B or Part D plans reimburse for these items, Medicaid will not pay.

Limited products in these therapeutic class(es) are covered:

1. OTC Vitamin D preparations
2. OTC Vitamin E preparations

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Supersedes

TN# 05-40

SUPERSEDES: TN- 05-40

AMLUNT, 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:

3. OTC Niacin preparations
4. OTC Calcium Replacement Agents
5. OTC Magnesium Replacement Agents
6. OTC Phosphate Replacement Agents
7. OTC Iron Replacement Agents
8. Normal Saline and Heparin flushes
9. Diabetic Supplies
10. Family Planning Items
11. Influenza vaccines.

G. **Drugs for Erectile Dysfunction.** Effective January 1, 2006, the Medicaid Program terminates coverage and reimbursement of prescription drugs when used for the treatment of sexual or erectile dysfunction. Erectile dysfunction drugs will only be covered when used for the treatment of other conditions or indications approved by the FDA.

H. **Monthly Prescription Limit.** Effective February 1, 2011, a monthly prescription limit is established.

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 homes and ICF-DD facilities; 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.

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HCF# 179 <u>10-79</u>	

TN# 10-79 Approval Date 3-9-11 Effective Date 1-1-11

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TN# 10-69

SUPERSEDES: TN- 10-69