

Department of Health & Human Services  
Centers for Medicare & Medicaid Services  
61 Forsyth St., Suite 4T20  
Atlanta, Georgia 30303-8909



---

March 25, 2011

Ms. Roberta K. Bradford  
Deputy Secretary for Medicaid  
Agency for Health Care Administration  
2727 Mahan Drive, Mail Stop #8  
Tallahassee, FL 32308

Re: Florida Title XIX State Plan Amendment, Transmittal #10-016

Dear Ms. Bradford:

This is to affirm approval of the above referenced State Plan Amendment which was submitted to the Regional Office on December 27, 2010. The effective date of October 1, 2010 has been accepted.

Enclosed for your records is a copy of the letter submitted to the State by Larry Reed, Director, Division of Pharmacy informing Florida of the approval, the original signed 179 with the "pen and Ink" changes to block ?a and copy of the approved plan pages.

If you have any additional question regarding this amendment, please contact Etta Hawkins at 404-562-7429.

Sincerely,

//s//

Jackie Glaze  
Associate Regional Administrator  
Division of Medicaid & Children's Health Operations

Department of Health & Human Services  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop S2-26-12  
Baltimore, Maryland 21244-1850



Center for Medicaid, CHIP and Survey & Certification  
Disabled and Elderly Health Programs Group

---

March 21, 2011

Ms. Roberta K. Bradford  
Deputy Secretary for Medicaid  
Agency for Health Care Administration  
2727 Mahan Drive, Mail Stop #8  
Tallahassee, FL 32308

Dear Ms. Bradford:

We have reviewed Florida State Plan Amendment (SPA) 10-016, Prescribed Drugs, received in the Regional Office on December 27, 2010. This amendment proposes to provide coverage for legend drugs which are now classified as over-the-counter medications and add coverage for shingles vaccine. In addition, this amendment makes several editorial and structural changes, including deleting outdated language concerning expired supplemental rebate agreements and value-added supplemental rebate agreements, updating the Prescribed Drugs section and revising the CFR citations.

We are pleased to inform you that the amendment is approved, effective October 1, 2010. In addition, per your March 2, 2011 e-mail, we made the requested changes to block eight on the HCFA-179 form.



A copy of the HCFA-179 form, as well as the pages approved for incorporation into the Florida state plan, will be forwarded by the Atlanta Regional Office. If you have any questions regarding this amendment, please contact Terry Simananda at (410) 786-8144.

Sincerely,

/s/

Larry Reed  
Director  
Division of Pharmacy

cc: Jackie Glaze, ARA, DMCHO, Atlanta Regional Office  
Etta Hawkins, Atlanta Regional Office

<b>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL</b>		1. TRANSMITTAL NUMBER: 2010-016	2. STATE Florida
<b>FOR: HEALTH CARE FINANCING ADMINISTRATION</b>		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE October 1, 2010	
5. TYPE OF PLAN MATERIAL (Check One):  <input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)			
6. FEDERAL STATUTE/REGULATION CITATION: Section 1927 of the Act		7. FEDERAL BUDGET IMPACT: (in thousands) No Fiscal Impact	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A Page 46 and 46a, Attachment 3.1-B Page 45 and 45a		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Attachment 3.1-A Page 46 and 46a, Attachment 3.1-B Page 45 and 45a	
10. SUBJECT OF AMENDMENT: Update to Pharmacy Program Policy			
11. GOVERNOR'S REVIEW (Check One): <input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input checked="" type="checkbox"/> OTHER, AS SPECIFIED: <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED                      Reviewed by the Deputy Secretary for Medicaid <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL                      who is the Governor's designee.			
12. SIGNATURE OF STATE AGENCY OFFICIAL: 		16. RETURN TO: Ms. Roberta K. Bradford Deputy Secretary for Medicaid Agency for Health Care Administration 2727 Mahan Drive, Mail Stop #8 Tallahassee, FL 32308  Attention: Robin Ingram	
13. TYPED NAME: Ms. Roberta K. Bradford			
14. TITLE: Deputy Secretary for Medicaid			
15. DATE SUBMITTED: 12/27/10			
<b>FOR REGIONAL OFFICE USE ONLY</b>			
17. DATE RECEIVED: 12/27/10		18. DATE APPROVED: 03/21/11	
<b>PLAN APPROVED - ONE COPY ATTACHED</b>			
19. EFFECTIVE DATE OF APPROVED MATERIAL: 10/01/10		20. SIGNATURE OF REGIONAL OFFICIAL: 	
21. TYPED NAME: Jackie Glaze		22. TITLE: Associate Regional Administrator Division of Medicaid & Children's Health Opns	
23. REMARKS:  Approved with following changes as authorized by State Agency on email dated 03/02/11:  <b>Block #8 Changed to read:</b> Atch 3.1-A Pages 46 and 46a; Atch 3.1-B pages 45 and 45a; Atch 4.19-B page 4  <b>Block #9 Changed to read:</b> Atch 3.1-A Pages 46 and 46a; Atch 3.1-B pages 45 and 45a; Atch 4.19-B page 4			

**PRESCRIBED DRUGS:**

Attachment 3.1-A

**Preferred Drug List with Prior Authorization:** In accordance with Florida Statute 409.91195 and pursuant to 42 U.S.C. s1396r-8, there is created a preferred drug list with prior authorization for drugs not included on the preferred drug list. The makeup and appointment authority for the Pharmaceutical and Therapeutic Committee is modified to comply with 42 U.S.C. s1396r-8.

**Prior Authorization Requirements:**

In accordance with Florida Statute 409.912, prior authorization requirements may be established for certain drug classes, particular drugs, or medically accepted indications for uses and doses.

**State Supplemental Rebates:**

Florida Statute 409.912 authorizes the state to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act. The agreement to be used between the State of Florida and drug manufacturers for supplemental rebates for drugs provided to the Medicaid population has been reviewed and authorized by the Centers for Medicare and Medicaid Services.

**Prescription Discount Programs:** In accordance with Florida Statutes 409.9066, Medicare Prescription Discount Program, and as provider enrollment criteria are developed at the discretion of the Agency, it is required as a condition of Medicaid provider enrollment that Medicaid participating pharmacy providers give price discounts to Medicare recipients who are Florida residents.

Amendment 2010-016  
Effective 10/1/10  
Supersedes 2005-004  
Approved 3-21-11

**PRESCRIBED DRUGS:**

Attachment 3.1-B

**Preferred Drug List with Prior Authorization:** In accordance with Florida Statute 409.91195 and pursuant to 42 U.S.C. s1396r-8, there is created a preferred drug list with prior authorization for drugs not included on the preferred drug list. The makeup and appointment authority for the Pharmaceutical and Therapeutic Committee is modified to comply with 42 U.S.C. s1396r-8.

**Prior Authorization Requirements:**  
In accordance with Florida Statute 409.912, prior authorization requirements may be established for certain drug classes, particular drugs, or medically accepted indications for uses and doses.

**State Supplemental Rebates:**  
Florida Statute 409.912 authorizes the state to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act. The agreement to be used between the State of Florida and drug manufacturers for supplemental rebates for drugs provided to the Medicaid population has been reviewed and authorized by the Centers for Medicare and Medicaid Services.

**Prescription Discount Programs:** In accordance with Florida Statutes 409.9066, Medicare Prescription Discount Program, and as provider enrollment criteria are developed at the discretion of the Agency, it is required as a condition of Medicaid provider enrollment that Medicaid participating pharmacy providers give price discounts to Medicare recipients who are Florida residents.

Amendment 2010-016  
Effective 10-01-10  
Supersedes 2005-004  
Approved 3-21-11

**Covered Legend Drugs:**

Covered outpatient drugs are those produced by any manufacturer that has entered into and complies with an agreement under Section 1927(a) of the Act, and are prescribed for a medically accepted indication. Drugs must be prescribed and dispensed in accordance with medically accepted indications for uses and dosages.

Coverage for immunizations is limited to the following recipients who are not covered by Medicare Part D:

- Influenza and pneumococcal vaccine for institutionalized recipients age 21-64 and
- Herpes Zoster (Shingles) vaccine for institutionalized recipients age 60-64

Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit –Part D.

As provided by Section 1927(d)(2) of the Act, certain outpatient drugs may be excluded from coverage. Those excluded are DESI drugs; experimental drugs; anorectics (unless prescribed for an indication other than obesity); non-legend drugs (except as specified below), and any drugs for which the manufacturer has not entered into rebate agreements with the Department of Health and Human Services, the Veteran’s Administration and the Public Health Service.

**The following excluded drugs are covered:**

- (a) agents when used for anorexia, weight loss, weight gain
- None of the drugs under this drug class are covered*
  
- (b) agents when used to promote fertility
- None of the drugs under this drug class are covered*
  
- (c) agents when used for cosmetic purposes or hair growth
- None of the drugs under this drug class are covered*
  
- (d) agents when used for the symptomatic relief cough and colds
- Some drug categories covered under the drug class*
  - Legend cough and cold preparations, including antitussives, decongestants, and expectorants are covered for recipients under the age of 21 years.
  - Legend or OTC single entity guaifenesin products are covered for all recipients.
  
- (e) prescription vitamins and mineral products, except prenatal vitamins and fluoride
- Some drug categories covered under the drug class*
  - Legend vitamin and mineral products are covered for dialysis patients.
  
- (f) nonprescription drugs
- Some drug categories covered under the drug class*
  - Insulin; aspirin; aluminum and calcium products used as phosphate binders; sodium chloride for specific medical indications for all recipients
  - Ferrous sulfate, gluconate, or fumarate for non-institutionalized recipients.

Amendment 2010-016  
 Effective 10/01/2010  
 Supersedes 2005-013  
 Approved 3-21-11  
 Revised Submission: 03/04/2011

When prescribed, the following OTC medications that have previously been legend drugs are covered:

- Urinary analgesic
- Proton pump inhibitor
- Smoking cessation and nicotine replacement products (for non-Part D eligible recipients)
- Topical antiparasitics
- Vaginal antifungals
- Select OTC single-entity antihistamines and antihistamine-decongestant (two ingredients only) are covered for all recipients.

(g) 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

*None of the drugs under this drug class are covered*

(h) barbiturates

*All of the drugs under this drug class are covered*

(i) benzodiazepines

*All of the drugs under this drug class are covered*

(j) smoking cessation for non-dual eligibles as Part D will cover

*Some drugs categories covered under the drug class*

- Approved smoking cessation and nicotine replacement products are covered services (for non-Part D eligibles).
- Approved smoking cessation and nicotine replacement products are covered services (for non-Part D eligibles). The Medicaid agency will provide coverage of prescription and over-the-counter (OTC) smoking/tobacco cessation covered outpatient drugs for pregnant women as recommended in "Treating Tobacco Use and Dependence - 2008 Update: A Clinical Practice Guideline" published by the Public Health Service in May 2008 or any subsequent modification of such guideline

**Drug Rebate Agreement:** The state is in compliance with Section 1927 of the Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for drug rebate agreements:

- The drug file permits coverage of participating manufacturers' drugs.
- Compliance with the reporting requirements for state utilization information and restrictions to coverage.
- A supplemental rebate agreement, Version 07/01/2005, between the state and a drug manufacturer that is separate from the drug rebate agreements of Section 1927 is authorized by the Centers for Medicare and Medicaid Services. The agreement to be used between the State of Florida and drug manufacturers for supplemental rebates for drugs provided to the Medicaid population has been reviewed and authorized by the Centers for Medicare and Medicaid Services. The state reports rebates from separate agreements to the Secretary for Health and Human Services. The state will remit the federal portion of any cash state supplemental rebates collected.
- Manufacturers are allowed to audit utilization data.
- The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.
- Prior authorization programs provide for a 24-hour turn-around on prior authorization from receipt of a completed request, and at least a 72-hour supply in emergency situations.

Amendment 2010-016

Effective 10/01/2010

Supersedes 2005-013

Approved 3-21-11

Revised Submission: 03/04/2011

**Covered Legend Drugs:**

Covered outpatient drugs are those produced by any manufacturer that has entered into and complies with an agreement under Section 1927(a) of the Act, and are prescribed for a medically accepted indication. Drugs must be prescribed and dispensed in accordance with medically accepted indications for uses and dosages.

Coverage for immunizations is limited to the following recipients who are not covered by Medicare Part D:

- Influenza and pneumococcal vaccine for institutionalized recipients age 21-64 and
- Herpes Zoster (Shingles) vaccine for institutionalized recipients age 60-64

Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit –Part D.

As provided by Section 1927(d)(2) of the Act, certain outpatient drugs may be excluded from coverage. Those excluded are DESI drugs; experimental drugs; anorectics (unless prescribed for an indication other than obesity); non-legend drugs (except as specified below), and any drugs for which the manufacturer has not entered into rebate agreements with the Department of Health and Human Services, the Veteran’s Administration and the Public Health Service.

**The following excluded drugs are covered:**

- (a) agents when used for anorexia, weight loss, weight gain
- None of the drugs under this drug class are covered*
  
- (b) agents when used to promote fertility
- None of the drugs under this drug class are covered*
  
- (c) agents when used for cosmetic purposes or hair growth
- None of the drugs under this drug class are covered*
  
- (d) agents when used for the symptomatic relief cough and colds
- Some drug categories covered under the drug class*
  - Legend cough and cold preparations, including antitussives, decongestants, and expectorants are covered for recipients under the age of 21 years.
  - Legend or OTC single entity guaifenesin products are covered for all recipients.
  
- (e) prescription vitamins and mineral products, except prenatal vitamins and fluoride
- Some drug categories covered under the drug class*
  - Legend vitamin and mineral products are covered for dialysis patients.
  
- (f) nonprescription drugs
- Some drug categories covered under the drug class*
  - Insulin; aspirin; aluminum and calcium products used as phosphate binders; sodium chloride for specific medical indications for all recipients
  - Ferrous sulfate, gluconate, or fumarate for non-institutionalized recipients.

Amendment 2010-016  
 Effective 10/01/2010  
 Supersedes 2005-013  
 Approved 3-21-11

Revised Submission: 03/04/2011



When prescribed, the following OTC medications that have previously been legend drugs are covered:

- Urinary analgesic
- Proton pump inhibitor
- Smoking cessation and nicotine replacement products (for non-Part D eligible recipients)
- Topical antiparasitics
- Vaginal antifungals
- Select OTC single-entity antihistamines and antihistamine-decongestant (two ingredients only) are covered for all recipients.

(g) 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

*None of the drugs under this drug class are covered*

(h) barbiturates

*All of the drugs under this drug class are covered*

(i) benzodiazepines

*All of the drugs under this drug class are covered*

(j) smoking cessation for non-dual eligibles as Part D will cover

*Some drugs categories covered under the drug class*

- Approved smoking cessation and nicotine replacement products are covered services (for non-Part D eligibles).
- Approved smoking cessation and nicotine replacement products are covered services (for non-Part D eligibles). The Medicaid agency will provide coverage of prescription and over-the-counter (OTC) smoking/tobacco cessation covered outpatient drugs for pregnant women as recommended in "Treating Tobacco Use and Dependence - 2008 Update: A Clinical Practice Guideline" published by the Public Health Service in May 2008 or any subsequent modification of such guideline

**Drug Rebate Agreement:** The state is in compliance with Section 1927 of the Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for drug rebate agreements:

- The drug file permits coverage of participating manufacturers' drugs.
- Compliance with the reporting requirements for state utilization information and restrictions to coverage.
- A supplemental rebate agreement, Version 07/01/2005, between the state and a drug manufacturer that is separate from the drug rebate agreements of Section 1927 is authorized by the Centers for Medicare and Medicaid Services. The agreement to be used between the State of Florida and drug manufacturers for supplemental rebates for drugs provided to the Medicaid population has been reviewed and authorized by the Centers for Medicare and Medicaid Services. The state reports rebates from separate agreements to the Secretary for Health and Human Services. The state will remit the federal portion of any cash state supplemental rebates collected.
- Manufacturers are allowed to audit utilization data.
- The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.
- Prior authorization programs provide for a 24-hour turn-around on prior authorization from receipt of a completed request, and at least a 72-hour supply in emergency situations.

Amendment 2010-016

Effective 10/01/2010

Supersedes 2005-013

Approved 3-21-11

Revised Submission: 03/04/2011

7/1/2004 PRESCRIBED DRUGS

Reimbursement for prescribed drug claims is made in accordance with the provisions of 42 CFR 447.516, pertaining to upper limits.

1. Reimbursement for covered drugs dispensed by a licensed pharmacy that has been approved as a Medicaid provider, or a physician filling his own prescriptions if there is no licensed pharmacy within a ten mile radius of his office, shall not exceed the lowest of:

- (a) For generic drugs:

- i. The amount established by CMS as the Federal Upper Limit (FUL) in accordance with 42 CFR §447.516. Payment for multiple-source drugs for which CMS has established upper limit will not exceed, in the aggregate, the set upper limits plus a dispensing fee.
- ii. If no FUL exists, the estimated acquisition cost (EAC) as established in Florida statute plus a dispensing fee; the state maximum allowable cost (SMAC) plus a dispensing fee; or the provider's usual and customary charges to the general public (non-Medicaid).
- iii. Products that are prohibited from generic substitution under state statutes may be declared "medically necessary" and reimbursed at the appropriate rate from the drug pricing file.

- (b) For brand name drugs:

The estimated acquisition cost for the drug plus a dispensing fee; the SMAC, plus a dispensing fee; or the provider's usual and customary charges to the general public (non-Medicaid).

- (c) 340B drugs:

Covered entities and Federally Qualified Health Centers that fill Medicaid patient prescriptions with 340B drugs must bill Medicaid for reimbursement at Actual Acquisition Cost plus the state allowable dispensing fee.

2. Definitions

- (a) EAC - Estimated Acquisition Cost (EAC) is the Agency's best estimate of what price providers generally and currently are paying for a drug. Effective July 1, 2008, the State of Florida reimburses, in addition to a dispensing fee, at the lesser of the average wholesale price (AWP) minus 16.4%; the wholesaler acquisition cost (WAC) plus 4.75%; the federal upper limit (FUL); or the state maximum allowable cost per unit (SMAC). The usual and customary (UAC) charge billed by the provider will be the applicable charge, if lower than the above allowed amounts.
- (b) FUL - Federal upper limit of payment as established by the Centers for Medicare and Medicaid Services (CMS) for multiple source drugs.

Amendment 2010-016  
 Effective 10/1/10  
 Supersedes 2008-015  
 Approval: 3-21-11