

## **Table of Contents**

**State/Territory Name: Florida**

**State Plan Amendment (SPA) #: 13-007**

This file contains the following documents in the order listed:

- 1) Regional Office Follow-up Approval Letter
- 2) Pharmacy Approval Letter
- 3) CMS 179 Form
- 4) Approved SPA Pages
- 5) Drug Rebate

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
Atlanta Regional Office  
61 Forsyth Street, Suite 4T20  
Atlanta, Georgia 30303



**DIVISION OF MEDICAID & CHILDREN'S HEALTH OPERATIONS**

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September 12, 2013

Mr. Justin Senior  
Deputy Secretary for Medicaid  
Agency for Health Care Administration  
2727 Mahan Drive, Mailstop #20  
Tallahassee, Florida 32308

Attention: April Cook

RE: Title XIX State Plan Amendment, FL 13-007

Dear Mr. Senior:

This is to affirm approval of the above referenced State Plan Amendment which was submitted to the Regional Office on June 17, 2013. The State's requested effective date of August 1, 2013 has been accepted.

Enclosed for your records are:

1. a copy of the approval letter dated September 10, 2013 that was submitted to the State by Larry Reed, Director, Division of Pharmacy;
2. the original signed 179; and
3. the approved plan pages.

If you have any additional questions regarding this amendment, please contact Etta Hawkins, State Coordinator for Florida, at 404-562-7429.

Sincerely,

//s//

Charna R. Pettaway  
Acting Associate Regional Administrator  
Division of Medicaid & Children's Health Operations

Enclosure(s)

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



## **Disabled & Elderly Health Programs Group**

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September 10, 2013

Justin M. Senior  
Deputy Secretary for Medicaid  
Agency for Health Care Administration  
2727 Mahan Drive, Mail Stop #8  
Tallahassee, FL 32308  
Attention: April Cook

Dear Mr. Senior:

We have reviewed Florida State Plan Amendment (SPA) 13-007, Supplemental Rebate Agreement, received in the Regional Office on June 17, 2013. This amendment proposed to update the Supplemental Rebate Agreement to include rebate payments generated by Managed Care Organization (MCO) generated prescriptions.

We are pleased to inform you that the amendment is approved, effective August 1, 2013. A copy of the CMS-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, Atlanta Regional Office  
Etta Hawkins, Atlanta Regional Office

<b>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL</b>		1. TRANSMITTAL NUMBER: 2013-007	2. STATE Florida
FOR: HEALTH CARE FINANCING ADMINISTRATION		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 August 1, 2013	
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: 42 U.S.C. 1395 as described in 42 U.S.C. 1396b(m)		7. FEDERAL BUDGET IMPACT: (in thousands) FFY 2013-2014    no fiscal impact FFY 2014-2015    no fiscal impact	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A pages 46-46.a16 and 3.1-B pages 45-45.a16 (includes Rebate Agreement, which is new)		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Attachment 3.1-A pages 46-46.a1 and 3.1-B pages 45-45.a1	
10. SUBJECT OF AMENDMENT: Supplemental Rebate Agreement			
11. GOVERNOR'S REVIEW (Check One):			
<input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL		<input checked="" type="checkbox"/> OTHER, AS SPECIFIED: Reviewed by the Deputy Secretary for Medicaid who is the Governor's designee.	
12. SIGNATURE OF STATE AGENCY OFFICIAL: //s//		16. RETURN TO: Mr. Justin M. Senior Deputy Secretary for Medicaid Agency for Health Care Administration 2727 Mahan Drive, Mail Stop #8 Tallahassee, FL 32308	
13. TYPED NAME: Mr. Justin M. Senior		Attention: April Cook	
14. TITLE: Deputy Secretary for Medicaid			
15. DATE SUBMITTED: 06-13-13			
<b>FOR REGIONAL OFFICE USE ONLY</b>			
17. DATE RECEIVED: 06-17-13		18. DATE APPROVED: 09-10-13	
<b>PLAN APPROVED - ONE COPY ATTACHED</b>			
19. EFFECTIVE DATE OF APPROVED MATERIAL: 08/01/13		20. SIGNATURE OF REGIONAL OFFICIAL: //s//	
21. TYPED NAME: Charna R. Pettaway		22. TITLE: Acting Associate Regional Administrator Division of Medicaid & Children Health Opns	
23. REMARKS:  Approved with the following changes to items 8 and 9 as authorized by State Agency e-mail dated 09/10/13: Block #8 Changed to read: Attachment 3.1-A pages 46-46.a1 and Attachment 3.1-B pages 45 and 45.a1. Block #9 Changed to read: Attachment 3.1-A pages 46-46.a1 and Attachment 3.1-B pages 45 and 45.a1.			

**PRESCRIBED DRUGS:**

**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 which 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 as provided by Section 1935(d)(1) of the Act.

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), insulin, aspirin, aluminum and calcium products used as phosphate binders, sodium chloride for specific medical indications; 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.

As provided by Section 1935(d)(2) of the ACT:

**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 drugs 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

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Supersedes 2013-001  
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- 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; 650mg acetaminophen tablets; aluminum and calcium products used as phosphate binders; sodium chloride for specific medical indications for all recipients

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
  - OTC single-entity antihistamines (Loratidine and Cetirizine with age restrictions on liquids) and antihistamine-decongestant combinations (Loratidine D and Cetirizine D with age restrictions on liquids).
- (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
- (Except for dual eligible individuals effective January 1, 2013 when used in the treatment of epilepsy, cancer or a chronic mental health disorder as Part D will cover those indications.)*
- (i) benzodiazepines
- (Except for dual eligible individuals effective January 1, 2013 as Part D will cover all indications.)*
- (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.

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- A supplemental rebate agreement, Version 05/20/2013, 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.

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