

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



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August 2, 2011

Mr. R. Bob Mullins, Jr., MD  
Commissioner  
Alabama Medicaid Agency  
501 Dexter Avenue  
Post Office Box 5624  
Montgomery, Alabama 36103-5624

Re: Alabama Title XIX State Plan Amendment, Transmittal #11-011

Dear Dr. Mullins:

This is to affirm approval of the above referenced State Plan Amendment which was submitted to the Regional Office on May 10, 2011. The State's requested effective date of June 1, 2011 has been accepted.

Enclosed for your records are:

1. a copy of the approval letter dated July 29, 2011 that was submitted to the State by Larry Reed, Director, Division of Pharmacy;
2. the original signed 179; and
3. the approved plan pages.

A companion letter is also being issued with this approval to address coverage issues identified during the review of this SPA.

If you have any additional questions regarding this amendment, please contact Maria Drake, State Coordinator for Alabama, at 404-562-3697.

Sincerely,

/s/

Jackie Glaze  
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



**Center for Medicaid, CHIP and Survey & Certification**

**Disabled and Elderly Health Programs Group**

July 29, 2011

Mr. R. Bob Mullins, Jr., MD  
Commissioner  
Alabama Medicaid Agency  
501 Dexter Avenue  
Post Office Box 5624  
Montgomery, Alabama 36103-5624

Dear Dr. Mullins:

We have reviewed Alabama's State Plan Amendment (SPA) 11-011 submitted to the Atlanta Regional Office on May 10, 2011. Based on the information provided, we are pleased to inform you that the SPA is approved. This amendment proposes to provide coverage of tobacco cessation products for pregnant women. The effective date of this SPA is June 1, 2011.

A copy of the CMS-179 form as well as the page approved for incorporation into Alabama's state plan will be forwarded by the Atlanta Regional Office. If you have any questions regarding this amendment, please contact Madlyn Kruh at (410) 786-3239.

Sincerely,

/ s /

Larry Reed  
Director  
Division of Pharmacy

cc: Jackie Glaze, Acting ARA, Atlanta Regional Office  
Maria Drake, Atlanta Regional Office

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



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August 2, 2011

Mr. R. Bob Mullins, Jr., MD  
Commissioner  
Alabama Medicaid Agency  
501 Dexter Avenue  
Post Office Box 5624  
Montgomery, Alabama 36103-5624

Re: Alabama Title XIX State Plan Amendment, Transmittal #11-011  
Companion Letter

Dear Dr. Mullins:

This letter is being sent as a companion to our approval of Alabama State Plan Amendment (SPA) AL 11-011 that was submitted to add coverage of smoking cessation products for pregnant females. During our review of AL 11-011, we noted that Attachment 3.1-A, page 5.12.1 does not meet comprehensiveness requirements. Based on that review, it was determined that this page is not consistent with the Medicaid statutory and regulatory requirements described below. While we are proceeding with the approval of Alabama SPA 11-011, this letter follows up on this matter as we want to work with you to resolve these issues.

### **Statutory and Regulatory Requirements**

Section 1902(a) of the Social Security Act (the Act) requires that States have a State plan for medical assistance that meets certain federal requirements that set out a framework for the State program.

Section 1902(a)(30)(A) of the Act requires that States have methods and procedures in place to assure that payments to providers are consistent with efficiency, economy, and quality of care. To be comprehensive, payment methodologies should be understandable, clear, and unambiguous. In addition, because the plan is the basis for FFP, it is important that the plan language provide an auditable basis for determining whether payment is appropriate.

42 CFR 430.10 requires that the State plan be a comprehensive written statement that describes the nature and scope of the State's Medicaid program and that it contain all information necessary for CMS to determine whether the plan can be approved to serve as the basis for Federal financial participation (FFP) in the State program.

**State Plan Comprehensiveness on Attachment 3.1-A page 5.12.1**

1. Please remove from section (f), the following terminology “Non-DESI, non- repackaged drug with a current price by a manufacturer with a federal rebate agreement in the following classes” along with “Iron products, Niacin, and Calcium replacement preparations”.
2. Nutritionally complete products used for inborn errors of metabolism should be moved to a separate section and identified as covered as an Active Pharmaceutical Ingredients (APIs) when prescribed and compounded extemporaneously. Other nutritional products should not be in this section, they should be covered under home health.
3. Please remove (h) “DESI and IRS drugs which may be restricted at the State’s option in accordance with 1927 (d)(2) of the Social Security Act.”
4. Please change (j) to (i).

Within 90 days of the date of this letter, the State is required to submit a State plan amendment that resolves the issues, or a corrective action plan to resolve the issues, whichever is appropriate. During the 90-day period, we are happy to provide any technical assistance that the State requires. State plans that are not in compliance with requirements referenced above are grounds for initiating a formal compliance process.

If you have any questions or need any further assistance, please contact Madlyn Kruh at (410) 786-3239 or Maria Drake at (404) 562-3697.

Sincerely,

/s/

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

cc: Larry Reed, Director  
Division of Pharmacy


<b>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL</b>	1. TRANSMITTAL NUMBER: AL 11-011	2. STATE Alabama
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
FOR: HEALTH CARE FINANCING ADMINISTRATION	4. PROPOSED EFFECTIVE DATE June 1, 2011	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	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 CFR Section 447.15, 447.331 & Section 401, et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508), and Public Law 110-28 (SSA Sec. 1903(i)).	7. FEDERAL BUDGET IMPACT: Total Annual Cost: FY 11 \$102,810 FY 12 \$102,510
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A, pages 5.12.1 and 5.12b	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Attachment 3.1-A, pages 5.12.1 and 5.12b

10. SUBJECT OF AMENDMENT:  
This amendment will add coverage of smoking cessation products for pregnant females and references that telephonic counseling available via Alabama Department of Public Health's Quitline Program.

11. GOVERNOR'S REVIEW (Check One):  
 GOVERNOR'S OFFICE REPORTED NO COMMENT  
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED  
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL  
 OTHER, AS SPECIFIED:  
Governor's designee on file via letter with CMS

12. SIGNATURE OF STATE AGENCY OFFICIAL: 	16. RETURN TO: R. Bob Mullins, Jr., MD Commissioner Alabama Medicaid Agency 501 Dexter Avenue Post Office Box 5624 Montgomery, Alabama 36103-5624
13. TYPED NAME: R. Bob Mullins, Jr., MD	
14. TITLE: Commissioner	
15. DATE SUBMITTED: 5-10-11	

17. DATE RECEIVED: 5-10-11	18. DATE APPROVED: 07/29/11
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PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 06/01/11	20. SIGNATURE OF REGIONAL OFFICIAL: 
21. TYPED NAME: Jackie Glaze	22. TITLE: Associate Regional Administrator Division of Medicaid & Children's Health Opps

23. REMARKS:  
Approved with following change as authorized by State Agency on email and letter dated 07/11/11.  
**Block # 8 and 9 changed to read:** Attachment 3.1-A, page 5.12.1.  
**Block #10 changed to read:** This amendment will add coverage of smoking cessation products for pregnant females.

Limitation of Services

12. **Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.**
12. a. **Prescribed Drugs**
- (e) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations and others as specified by the Alabama Medicaid Agency.
    - Renal vitamins and vitamin preparations used in Total Parenteral Nutrition are covered.
  - (f) Non prescription drugs except for those specified by the Alabama Medicaid Agency.
    - Non-DESI, non-repackaged drugs with a current price by a manufacturer with a federal rebate agreement in the following classes are covered: Antacids and adsorbents, Anthelmintics, Nasal antiallergics, Topical antibiotics, Antidiarrhea agents, Topical antifungals, Antihistamines, Topical anti-inflammatory agents, Insulins, Iron preparations, Topical keratoplastic agents, Acetaminophen, Niacin, Nonsteroidal anti-inflammatory agents, Calcium replacement preparations, Topical scabicides and pediculicides, Optical vasoconstrictor agents, Proton Pump Inhibitors.
    - Nutritionally complete products, products used for inborn errors of metabolism, and other specialized nutritional products are covered with prior authorization.
  - (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.
  - (h) DESI and IRS drugs which may be restricted at the State's option in accordance with 1927(d)(2) of the Social Security Act.
  - (i) Benzodiazepines and barbiturates except for those specified by the Alabama Medicaid Agency.
    - Generic benzodiazepines (except estazolam) and generic barbiturates are covered.
  - (j) Agents when used to promote smoking cessation unless authorized for pregnant females women according to the Public Health Service guidelines "Treating Tobacco Use and Dependence: 2008 Update: A Clinical Practice Guideline, or any subsequent modification of such guideline.