



July 19, 2011

Dr. Jerry Dubberly, Chief
Medicaid Division
Georgia Department of Community Health
2 Peachtree Street
Atlanta, Georgia 30303

Re: Georgia State Plan Amendment, Transmittal #10-016

Dear Dr. Dubberly:

This is to affirm approval of the above referenced State Plan Amendment which was submitted to the Regional Office on October 7, 2010. The State's requested effective date of July 1, 2011 has been accepted.

Enclosed for your records are:

1. a copy of the approval letter dated July 14, 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.

If you have any additional questions regarding this amendment, please contact Carolyn Brown, State Coordinator for Georgia, at 404-562-7421.

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 S2-26-12
Baltimore, Maryland 21244-1850



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

July 14, 2011

Jerry Dubberly
Chief
Medicaid Division
Georgia Department of Community Health
2 Peachtree Street, NW
Atlanta, Georgia 30303

Dear Mr. Dubberly:

We have reviewed Georgia State Plan Amendment (SPA) 10-016 received in the Atlanta Regional Office of the Centers for Medicare and Medicaid Services (CMS) on October 7, 2010. Under this SPA, the State proposes to change its prescription drug reimbursement methodology for select specialty drugs. The State's reimbursement methodology will be determined by wholesaler/manufacturer data, a comparison to other State agencies' reimbursement information, and publicly available drug prices from other payers. The select specialty drug pharmacy rate applies to the following disease states that are rare and/or complex: rheumatoid arthritis, Crohn's disease, psoriasis, multiple sclerosis, neutropenia, anemia, growth hormone deficiency, cystic fibrosis, respiratory syncytial virus prevention, pulmonary hypertension hemophilia, cancer and orphan diseases. We are pleased to inform you that the Georgia SPA 10-016 is approved, effective July 1, 2011.



The Atlanta Regional Office will forward to you a copy of the CMS-179 form, as well as the pages approved for incorporation into the Georgia Medicaid State Plan. If you have any questions regarding this amendment, please contact Bernadette Leeds at (410) 786-9463.

Sincerely,

/s/

Larry Reed
Director
Division of Pharmacy

cc: Jackie Glaze, ARA, Atlanta Regional Office
Carolyn Brown, Atlanta Regional Office
Gia Compton, Georgia Department of Community Health

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL		1. TRANSMITTAL NUMBER: 10-016	2. STATE GEORGIA
FOR: HEALTH CARE FINANCING ADMINISTRATION		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE AND MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE November 1, 2010	
5. TYPE OF PLAN MATERIAL (<i>Check One</i>):			
<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 (<i>Separate Transmittal for each amendment</i>)			
6. FEDERAL STATUTE/REGULATION CITATION: 42CFR447.512		7. FEDERAL BUDGET IMPACT: a. FFY 2011 (\$235,956) FFY 2012 (\$714,587)	
"8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 4.19-B, Pg. 2		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>): Attachment 4.19-B, page 2	
10. SUBJECT OF AMENDMENT: SPECIALITY PHARMACY REIMBURSEMENT RATES			
11. GOVERNOR'S REVIEW (<i>Check One</i>):			
<input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> OTHER, AS SPECIFIED:			
<input checked="" type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATURE OF STATE AGENCY OFFICIAL: 		16. RETURN TO:	
13. TYPED NAME: JERRY DUBBERLY		Department of Community Health Medicaid Division 2 Peachtree Street, N.W. Atlanta, Georgia 30303-3159	
14. TITLE: CHIEF, Medicaid Division			
15. DATE SUBMITTED:			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED: 10-07-10		18. DATE APPROVED: 07/14/11	
PLAN APPROVED - ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: 07/01/11		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 the following changes as authorized by State Agency on emails dated 07/18/11: <u>Block # 4:</u> Changed to read: July 1, 2011 <u>Block #7</u> Changed to read: FFY 2011 \$(477,130.42) and FFY 2012 \$ (1,910,040.96) <u>Block #8</u> Changed to read: Attachment 4.19-B, pages 2, 2.1.a (new) and 2.1.b (new) <u>Block #9</u> Changed to read: Attachment 4.19-B, pages 2, 2.1.a (new) and 2.1.b (new)			

POLICY AND METHODS FOR ESTABLISHING PAYMENT RATES
FOR OTHER TYPES OF CARE OR SERVICES

d. Prescribed Drugs

1. Medicaid pays for prescribed legend and non-legend drugs authorized under the program. Reimbursement for covered multiple source drugs shall not exceed the lowest of:

- (a) The federal mandated upper limit for certain multiple source drugs as established and published by CMS plus a reasonable dispensing fee as established in item 2; or
- (b) The Georgia Maximum Allowable Cost (GMAC) as established by the Division for additional multiple source drugs plus a reasonable dispensing fee as established in item 2 below; or
- (c) The Georgia Estimated Acquisition Cost (GEAC) for multiple source drugs plus a reasonable dispensing fee as established in item 2 below; or
- (d) The usual and customary charge as defined below by the Division for the prescription or
- (e) The submitted ingredient cost plus the submitted dispensing fee.

Reimbursement for covered drugs other than multiple source drugs shall not exceed the lower of:

- (a) The GEAC for all other drugs plus a reasonable dispensing fee as established in item 2 below or
- (b) The usual and customary charge as defined by the Division for the prescription; or
- (c) The Select Specialty Pharmacy Rate (SSPR) as established by the Division for select specialty drugs plus a reasonable dispensing fee as established in item 2 below; or
- (d) Most Favored Nations rate submitted by the provider and accepted by the Department.

GEAC is defined as the average wholesale price (AWP) of the drug less an 11% discount for all drugs

The Division defines usual and customary as the lower of the lowest price reimbursed to the pharmacy by other third party payers (including HMOs); or the lowest price routinely offered to any segment of the general public. Donations or discounts provided to charitable organizations, or fees charged to or paid by federal or state funded programs are not considered usual and customary charges.

Select Specialty Pharmacy Rate (SSPR)

SSPR - Disease State and Pharmaceutical Inclusion

Selected pharmaceuticals that meet any of the following criteria are candidates for inclusion in the SSPR:

- 1. used to treat a Georgia Medicaid SSPR identified disease state;
- 2. available through limited distribution channels;
- 3. part of a complex care regimen;
- 4. carry a predicted annual cost of \$5000 or more per year; or
- 5. manufactured as a biological or large molecular product.

The SSPR applies to selected pharmaceuticals used to treat selected disease states that are rare and/or complex in nature and are treated by a pharmaceutical product that meets the Georgia Medicaid SSPR criteria. Georgia Medicaid SSPR identified disease states include the following:

1. Rheumatoid Arthritis
2. Crohn's Disease
3. Psoriasis
4. Multiple Sclerosis
5. Neutropenia
6. Anemia
7. Growth Hormone Deficiency
8. Cystic Fibrosis
9. Respiratory Syncytial Virus (RSV) Prevention
10. Pulmonary Hypertension
11. Hemophilia
12. Cancer
13. Orphan Diseases

SSPR - Rate Setting

The SSPR is an Estimated Acquisition Cost (EAC) for select specialty pharmaceuticals based on the product dispensed and the State's ability to ensure access to the medication at that reimbursement level. All other established lesser of payment methodologies and rules in the approved State Plan continue to apply.

The rate setting methodology will be an on-going process and incorporate the following components:

1. The specific drugs and corresponding disease states are identified
2. No later than thirty (30) days prior to the end of the quarter, publicly available specialty pharmacy reimbursement rates of other payers will be reviewed. This will include:
 - a. A review of publicly available specialty pharmacy reimbursement rates paid by up to two (2) other state Medicaid agencies pursuant to a CMS-approved state plan will be reviewed.
 - b. A review of specialty pharmacy reimbursement levels publicly available paid by up to two (2) commercial payers will be conducted.
3. The proposed specialty rates will be compared to the Most Favored Nation Rates for providers currently dispensing the specialty pharmaceutical products
4. The above elements will be considered and the pricing point set at a level no lower than where providers in the marketplace are currently providing the product.
5. Fifteen (15) calendar days prior to the end of the quarter, the specialty pharmacy reimbursement levels will be finalized by the Department.
6. No less than one (1) week prior to the end of the quarter the new rates will be published in the Pharmacy Services Manual.

7. Appeal Process: On an ongoing basis, providers are allowed to submit a request for reimbursement review.
 - a. Provider submits a Reimbursement Review Request Form
 - i. Provider submits two (2) most recent wholesaler invoices. If this is the first time a provider has dispensed said product within the last three (3) months, then one (1) invoice will be accepted..
 - ii. The Provider will attest to that product is not available to the provider in the market at the published rate.
 - b. The Department will review the invoices and compare to other dispensing providers within a geographical location.
 - i. The Department will work with wholesalers and other providers to discern the availability of the product at the specialty pharmacy reimbursement rate in the marketplace.
 - ii. The Department will identify any other provider in the geographic area that are accepting the specialty pharmacy reimbursement rate and coordinate access to those providers for any affected members.
 - iii. Absent other providers accepting the specialty pharmacy reimbursement rate, the Department will adjust the specialty pharmacy reimbursement rate.
 - c. The provider will be notified within five (5) business days of the determination of the request for Reimbursement Review.
 8. Any resulting adjustment in the specialty pharmacy reimbursement rate will be updated in the claims processing system within ten (10) business days of the determination.
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2. The dispensing fee for profit and non-profit community pharmacies is based on periodic surveys of pharmacy operating costs including professional salaries and fees, overhead costs and reasonable profit. Between these periodic surveys, the Division, in consultation with the Governor's Office of Planning and Budget, reviews the fee. When appropriate, the fee is adjusted based on an inflation factor. The Medicaid dispensing fee shall be \$4.63 for profit pharmacies and \$4.33 for non-profit pharmacies. The dispensing fee paid by the Division shall be subject to the usual and customary charge as defined by the Division above and shall not exceed the lower of submitted charges.