

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Myers</i>	DATE <i>2-4-08</i>
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DIRECTOR'S USE ONLY		ACTION REQUESTED	
1. LOG NUMBER <i>000408</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____		
2. DATE SIGNED BY DIRECTOR <i>CC: Deps, Ms. Forlmer</i> <i>Cleared 12/17/08 letter</i> <i>attached.</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>4-21-08</i>		
		<input type="checkbox"/> FOIA DATE DUE _____	
		<input type="checkbox"/> Necessary Action	

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			

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1. LOC NUMBER <i>000408</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____		
2. DATE SIGNED BY DIRECTOR <i>CC: Deps, Ms. Forkner</i>		<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>4-21-08</i> <input type="checkbox"/> FOIA DATE DUE _____ <input type="checkbox"/> Necessary Action	

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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 and State Operation

JAN 31 2008

Ms. Emma Fortner
Director

South Carolina Department of Health and Human Services
Post Office Box 8206
Columbia, South Carolina 29202-8206

RECEIVED

FEB 04 2008
Department of Health & Human Services
OFFICE OF THE DIRECTOR

Dear Ms. Fortner:

We have reviewed South Carolina's State Plan Amendment (SPA) 07-010 received in the Atlanta Regional Office on November 20, 2007. Under this SPA, South Carolina proposes to revise its State Maximum Allowable Costs (SMAC) to the Average Manufacturer's Price (AMP) less 10 percent. Additionally, this SPA would allow the State to apply an enhanced dispensing fee of \$9.94 for independent pharmacy providers and \$7.73 for institutional pharmacy providers when the drug payment is based upon AMP. It would also delete the dispensing fee for drugs dispensed by physicians. You requested an effective date of January 1, 2008.

While we appreciate the information that you have provided to us, it is insufficient for us to approve this SPA. In order for us to proceed, we need additional information as indicated below:

Court Injunction Regarding AMP Data

1. On December 19, 2007, the United States District Court for the District of Columbia issued an Order enjoining the Department of Health and Human Services from:
 - a. Undertaking any and all action to implement the AMP Rule to the extent such action affects Medicaid reimbursement rates for retail pharmacies under the Medicaid program, and
 - b. Posting any AMP data on a public website or otherwise disclosing any AMP data to any individuals or entities, including but not limited to States and their representatives or agencies.

In light of the Court's Order and the injunction regarding the disclosure of AMP data, please explain how the proposed South Carolina SPA 07 010 is a workable option. In addition, please explain how the SPA is consistent with the Court's Order.

2. Since South Carolina SPA 07-010 is proposing an increase in dispensing fees for independent and institutional pharmacy providers for certain drugs, this may result in an

increase in Federal costs. Please explain your rationale for reporting \$0 for the Federal budget impact for Federal Fiscal Years 2008 and 2009 on your CMS 179.

3. For drugs with ingredient costs paid at AMP less 10 percent, you are proposing an increase in the dispensing fee from \$4.05 to \$9.94 for independent pharmacy providers and from \$3.15 to \$7.73 for institutional pharmacy providers.

- a. How have you determined that your proposed dispensing fees represent reasonable costs for independent and institutional pharmacy providers to dispense a drug to a Medicaid beneficiary in South Carolina in accordance with 42 Code of Federal Regulations (CFR) § 447.332 (a)?
- b. Please provide a detailed explanation of what costs of dispensing are included for these two pharmacy provider types.
- c. Please confirm how the methodology and cost data have been validated.

4. Please provide a clear explanation of your ingredient cost for multiple source drugs in Attachment 4.19-B Page 3b.

- a. Please explain what is meant when you refer to ingredient costs expressed as AMP less 10 percent. Do you mean you would use the actual AMP of each drug less 10 percent or use the new AMP-based FUL less 10 percent?
- b. How do you determine your SMAC? Are you planning to develop your SMAC using the AMP less 10 percent?
- c. How would either AMP less 10 percent or FUL less 10 percent represent a reasonable acquisition cost?

5. Federal regulation at 42 CFR §447.205(a), requires that the agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services. Please provide a copy of the public notice required for this reimbursement change. The public notice must precede the effective date of the SPA.

Please respond to the following State Plan funding questions.

State Plan Reimbursement Funding Questions

Section 1903(a)(1) of the Social Security Act provides that Federal financial participation is only available for expenditures made by States for services under the approved State Plan. To ensure that program dollars are used only to pay for Medicaid services, we are asking States to confirm to CMS that pharmacies retain 100 percent of the payments provided to them as indicated in attachment 4.19B. Specifically, please answer the following questions regarding the proposed amendment and current reimbursement made under the Medicaid plan for pharmacy providers:

- Do pharmacy providers retain all of the State and Federal Medicaid payments (including dispensing fees, ingredient costs, benefit management costs, etc.) or are providers obligated to return any portion of the Medicaid payment to the State or local government entity, or any other intermediary organization or entity?

- If pharmacy providers are obligated to return any portion of the payment, the State must provide a full description of the repayment methodology including: a complete list of pharmacy providers that return their payments; the amount or percentage of the payment; and the disposition and use of the funds once they are returned to the State (i.e. general revenue fund, medical services account, etc.)

Section 1902(a)(2) provides that the lack of adequate funds from local sources will not result in the lowering the amount, duration, scope, or quality of care and services available under the plan. Please describe how the State share of your Medicaid pharmacy payment in attachment 4.19B is funded, including the payments made under the proposed amendment. Specifically:

- Describe whether the State share is from appropriation from the legislature, through intergovernmental transfer agreements (IGT), certified public expenditures (CPE), provider taxes, or any other mechanism used by the State to provide the State share.
- Please provide your estimate of total expenditures and State share amount for your Medicaid pharmacy payments.
- If any of the State share is being funded by IGTs or CPEs, please fully describe the matching arrangement. If CPEs are used, please describe how the State verifies that the expenditures being certified are eligible for Federal matching funds in accordance with 42 CFR 433.51(b).

Section 1902(a)(30) of the Act requires that payments for services be consistent with efficiency, economy, and quality of care. Section 1903(a)(1) provides for FFP to States for expenditures for services under an approved State plan. If you are providing, or propose to provide under this amendment, an enhanced or supplemental payment to pharmacy providers under section 4.19B of the plan, please provide the following information:

- The total amount for each enhanced or supplemental payment provided to pharmacy providers and the precise service cost this payment is covering.
- Indicate whether there are public pharmacy providers and if they are receiving payments in accordance with attachment 4.19B that in the aggregate exceed its reasonable costs of providing services. If the payment exceeds the reasonable costs of services (for pharmacy that would be a reasonable dispensing fee and ingredient cost) please indicate whether the State recoups the excess and returns the Federal share of the excess to CMS on the quarterly expenditure report.

This request for additional information is made pursuant to Section 1915 (f) of the Social Security Act and will stop the 90-day period for CMS review and approval of a SPA. Upon receipt of your additional information, a new 90-day period will begin. In accordance with our guidelines to all State Medicaid Directors, dated January 2, 2001, we request that you provide a formal response to this request for additional information no later than 90-days from the date of this letter. If you do not provide us with a formal response by that date, we will conclude that the State has not established that the proposed SPA is consistent with all statutory and regulatory requirements and will initiate disapproval action on the amendment.

Because this amendment was submitted after January 2, 2001, and is effective on or after January 1, 2001, please be advised that we will defer Federal Financial Participation (FFP) for State payments made in accordance with this amendment until it is approved. Upon approval, FFP will be available for the period beginning with the effective date through the date of actual approval.

Under revised CMS procedures for processing pharmacy-related SPAs, we ask that you respond to this request for additional information via e-mail, fax, and hard copy. Please email your response to me at deirdre.duzor@cms.hhs.gov and to Bernadette Leeds at bernadette.leeds@cms.hhs.gov. Please fax your response to me at 410-786-6730. Also, please send hard copies to Elaine Elmore in the Atlanta Regional Office and to me at the address above.

If you have any questions regarding this request, please contact Bernadette Leeds at (410) 786-9463.

Sincerely,



Deirdre Duzor
Director

Division of Pharmacy
Disabled & Elderly Health Programs Group

c: Jay Gavens, Acting ARA, Atlanta Regional Office
Elaine Elmore, Atlanta Regional Office
Darlene Noonan, Atlanta Regional Office



State of South Carolina
Department of Health and Human Services

Mark Sanford
Governor

Emma Forkner
Director

December 17, 2008

Ms. Mary Kaye Justis, RN, MBA
Acting Associate Regional Administrator
Centers for Medicare & Medicaid Services
Division of Medicaid & Children's Health Operations
61 Forsyth Street, Suite 4T20
Atlanta, Georgia 30303-8909

Re: South Carolina Title XIX State Plan Amendment SC 07-010


This amendment establishes an enhanced dispensing fee to be used with any prescription that utilizes ingredient cost priced at Average Manufacturer's Price (AMP).

Dear Ms. Justis:

The South Carolina Department of Health and Human Services would like to withdraw State Plan Amendment SC 07-010 from CMS' review.

If you should have any questions, please contact Felicity Myers, Deputy Director of Medical Services at (803) 898-2501.

Sincerely,


Emma Forkner
Director

EF/mh

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St., Suite 4120
Atlanta, Georgia 30303-8909



December 18, 2008

Ms. Emma Forkner, Director
South Carolina Department of Health and Human Services
Post Office Box 8206
Columbia, South Carolina 29202-8206

Re: South Carolina Title XIX State Plan Amendment, Transmittal #07-010

Dear Ms. Forkner:

We accept your request, dated December 17, 2008, to withdraw the above State Plan Amendments. We are returning all Form HCFA-179s and the proposed plan pages.

If you have any questions regarding this amendment, please contact Elaine Elmore at (404) 562-7408.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Mary Kaye Justis', is written over the typed name.

Mary Kaye Justis, RN, MBA
Acting Associate Regional Administrator
Division of Medicaid & Children's Health Operations

Enclosures