DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO	DATE
Wells	12-13-10

DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER 10-263	[ ] Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR cc: Ms. Forkner, Deps, CMS file	[ ] Prepare reply for appropriate signature DATE DUE _____ [ ] FOIA DATE DUE _____ [X] 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.			

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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

DEC 1 0 2010

RECEIVED

DEC 1 3 2010

MEDICAID ELIGIBILITY & BENEFICIARY SERVICES Director

Emma Forkner
Director
South Carolina Department of Health and Human Services
P.O. Box 8206
Columbia, South Carolina 29202-8206

Dear Ms. Forkner:

We have reviewed South Carolina State Plan Amendment (SPA) 10-008 received in the Atlanta Regional Office on September 15, 2010. Under this SPA, the State proposes to establish a four-tier reimbursement structure for Medicaid covered injectable drugs administered in a physician office setting. The effective date for this SPA is October 1, 2010.

We appreciate the State's responses to the informal questions submitted to the Centers for Medicaid & Medicare Services (CMS) on November 10, and 17, 2010. We also acknowledge the State's submission of requested drug list information and various requested documents such as the public notices, revised CMS 179 form, expenditure information and further clarification regarding the State's certified public expenditures process. After review of the information and documents received, further clarification and additional information is needed before we can continue processing this SPA. Therefore, we are formally requesting additional information (RAI) pursuant to Section 1915(f) of the Social Security Act.

CMS 179 Form

1. Under the informal questions process, the State provided a revised CMS 179 with changes to Block 7: FFY 2011 ($2,706,840) and FFY 2012 ($0) for the Federal budget impact. Please enter an estimate for FFY 2012 via a revised CMS 179 or "pen and ink authorization" for the existing CMS 179 form.

State Plan Amendment Page: Attachment 4.19-B Item 5 Reimbursement Methodology Physician Services

2. Under the State plan amendment, Tier 1 is specified as follows:

> The first tier is comprised of select generics and injectable drugs in classes with therapeutic alternatives. It utilizes a variable fee schedule with Maximum Allowable Cost and/or Least Cost Alternative (MAC/LCA) pricing for appropriate reimbursement based on pharmaceutical acquisition costs.

a. In the State's response to the informal questions, the State submitted the requested list of drugs to be included in the State's selection of "generic and injectable drugs in classes with therapeutic alternatives" under the first tier. It is not clear what the State means by "select generics and injectable drugs in classes with therapeutic alternatives." Please further describe the criteria the State used or common factors considered to determine which drugs to include under Tier 1. In addition, please include a concise description in the State plan that clearly specifies the State's category of drugs for Tier 1 versus the other tiers.

b. The State also noted in its informal response that, "A combination of multiple sources including but not limited to Oncology Supply, OTN/McKesson Specialty, and Cardinal Health are compiled to determine the correct ingredient cost for the MAC/LCA Tier 1 calculation." It is not clear what the State means by Maximum Allowable Cost and/or Least Cost Alternative (MAC/LCA). Is this a State Maximum Allowance Cost? Please provide further clarification of this response and explain the term, MAC/LCA. In addition, please provide the rationale with supporting documentation the State used to determine that the proposed ingredient cost for the MAC/LCA for Tier 1 is the State's best estimate of the price that providers in the State are generally and currently paying for prescribed drugs.

c. In its informal response, the State responded that a variable fee schedule represents the appropriate reimbursement dollar amount for each drug in Tier 1 based on the ingredient cost which is independent of the ASP rate and therefore the ASP percentage may change from quarter to quarter. The State further responded that ingredient costs are used to calculate the brand drug margin and then subsequently apply an equivalent dollar margin to the lowest cost agent's ingredient cost within the entire therapeutic class (brand and generic). Please define "variable fee schedules" and explain how the fee schedules are determined and applied in Tier 1.

3. Under the State plan amendment, Tier 2 is specified as follows:

> The second tier comprises newer chemotherapy agents and higher cost drugs. These will be reimbursed at Average Sales Price (ASP) as published by the Centers for Medicare & Medicaid Services (CMS) plus 6%.

As requested under the informal questions, the State specified the drugs included in the State's selection of "newer chemotherapy agents and higher cost drugs" under the second tier. It is still not clear what the State means by "newer chemotherapy agents and higher cost drugs." Please describe the criteria the State used or common factors considered to determine which drugs to

include under the second tier. In addition, please include a concise description in the State plan that clearly specifies the State's category of drugs for the second tier versus the other tiers.

4. Under the State plan amendment, Tier 3 is specified as follows:

   All other drugs with ASP pricing will be reimbursed at ASP plus 10%

   As requested under the informal questions, the State submitted the drug list for the State's selection of "all other drugs with ASP pricing" under Tier 3. Please describe the criteria the State used or common factors considered to determine which drugs to include under Tier 3. In addition, please include a concise description in the State plan that clearly specifies the State's category of drugs for Tier 3 versus the other tiers.

   In the State's response, the State indicated that "Tier 3 is comprised of moderately priced agents and older drugs where there are often significant AWP/ASP differentials." The State further responded that "by increasing the profit margin from Tier 2 this ensures that providers are adequately reimbursed and is confirmed with an analysis using the ingredient costs." Please further discuss the State's rationale for an increased profit margin from ASP plus 6% to ASP plus 10% is necessary and is the State's best estimate of the price that providers in the State are generally and currently paying for prescribed drugs. Please submit documentation that supports the State's determination.

5. Under the informal questions, the State was requested to provide the rationale and documentation used to determine that the proposed ingredient cost at AWP minus 18 percent under Tier 4 is the State's best estimate of the price that providers in the State are generally and currently paying for prescribed drugs. The State responded that,

   > AWP has been the basis for reimbursement of Physician Administered Drugs for years with an annual review and update of pricing. SPA 10-008 would increase the frequency of the updates which will reduce the current lag in price realignment. The SCDHHS has experience favorable provider participation and access for our beneficiaries with this pricing method.

   Please further discuss the State's rationale for determining that AWP minus 18 percent under Tier 4 is consistent with the price that providers in the State are generally and currently paying for prescribed drugs. In addition, please submit documentation that supports the State's determination.

   As requested under the informal questions, the State submitted the drug list for the State's selection of "all other drugs under the Tier 4. Please describe the criteria the State used or common factors considered to determine which drugs to include under Tier 4. In addition, please include a concise description in the State plan that clearly specifies the State's category of drugs for Tier 4 versus the other tiers.

State Plan Reimbursement Funding Questions

Please respond to the following funding information request in relation to this proposed South Carolina SPA 10-008 for physician administered drugs.

6. CMS has reviewed the State's informal responses received on November 10 and 17, 2010. The revisions to the State plan do not comprehensively describe the cost identification methodology, allocation, and reconciliation process the State will undertake to identify total incurred cost. The State plan must also provide the level of cost the governmental provider will be reimbursed. In addition, the provider must have a cost-accounting system in place to appropriately identify, out of the total pool of costs incurred in providing services to all of its clients, only those that represent expenditures made on behalf of Medicaid beneficiaries. The state must provide all the components below for CMS review (including the cost reports):

    a. identification of the specific direct costs (salaries and fringes of the direct medical personnel and non-personnel direct medical supplies and equipment),

    b. the indirect cost rate used or identification of the specific indirect costs

    c. use of a statistically valid time study to identify the time spent providing medical services (if required),

    d. an allocation methodology to Medicaid,

    e. the methodology used to determine the interim payment amount,

    f. the reconciliation procedures between interim payments and the actual total costs at the provider level on annual basis,

    g. a description of the certification process and a copy of the certification forms used by each provider type, and

    h. a process to return any interim overpayment in FFP to CMS.

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.

We ask that you respond to this request for additional information via the Atlanta Regional Office SPA/Waiver mailbox at SPA_Waivers_Atlanta_R04@cms.hhs.gov with a copy to me at larry.reed@cms.hhs.gov, Bernadette Leeds of the Division of Pharmacy at bernadette.leeds@cms.hhs.gov and Tandra Hodges of the Atlanta Regional Office at tandra.hodges@cms.hhs.gov.

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

Sincerely,

Kim Howell for Larry Reed

Larry Reed
Director
Division of Pharmacy

cc: Jackie Glaze, ARA, Atlanta Regional Office
Tandra Hodges, Atlanta Regional Office
Valeria Williams, South Carolina Department of Health and Human Services

ORIGINAL

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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

DEC 1 0 2010

RECEIVED

DEC 1 7 2010
Director's
MEDICAID ELIGIBILITY
& BENEFICIARY SERVICES

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Director
South Carolina Department of Health and Human Services
P.O. Box 8206
Columbia, South Carolina 29202-8206

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Larry Reed
Director
Division of Pharmacy

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