

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>12/1/10</i>	DATE <i>12-2-10</i>
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DIRECTOR'S USE ONLY		ACTION REQUESTED	
1. LOG NUMBER <i>1001249</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____		
2. DATE SIGNED BY DIRECTOR <i>CC: Ms. Forlmer, CMS file Cleared 1/31/10, see attached note @ top of page.</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>1/31/10</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.			



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator

Washington, DC 20201

DEC 01 2010

RECEIVED

Ms. Emma Forkner
Director

South Carolina Department of Health and Human Services
P.O. Box 8206

Columbia, SC 29202-8206

DEC 02 2010

Department of Health & Human Services
OFFICE OF THE DIRECTOR

Dear Ms. Forkner:

I am responding to your request to approve South Carolina State plan amendment (SPA) 10-009, received by the Centers for Medicare & Medicaid Services (CMS) on August 30, 2010. This SPA would increase the estimated acquisition cost (EAC) from average wholesale price (AWP) minus 10 percent to wholesale acquisition cost (WAC) plus 12.5 percent, effective October 1, 2010. South Carolina proposed this increase in drug reimbursement rates following the settlement in the *New England Carpenters Health Benefit Fund v. First Databank, Inc.* litigation.

I am unable to approve this SPA because it does not comply with section 1902(a)(30)(A) of the Social Security Act (the Act), which requires, in part, that States have methods and procedures in place that payment rates are consistent with efficiency, economy, and quality of care. Under that authority, the Secretary has issued regulations prescribing State rate setting procedures and requirements. Longstanding requirements of Federal regulations presently codified at 42 Code of Federal Regulations (CFR) 447.512 provide that payments for drugs are to be based on the ingredient cost of the drug and a reasonable dispensing fee. States establish their reimbursement methodologies for the ingredient cost of a drug through the EAC. The definition of EAC, presently codified at 42 CFR 447.502 is "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers."

In support of its proposal, the State indicated that it submitted this SPA in response to a State directive contained in the South Carolina 2010-2011 Appropriations Act. The directive requires the State to submit a SPA to CMS by October 31, 2010, that proposes, in part, to increase the EAC from AWP minus 10 percent to WAC plus 12.5 percent. The directive allows the State to maintain its reimbursement at the rates that were in effect prior to the *First Databank, Inc.* settlement. However, the State's interpretation of the *First Databank, Inc.* settlement is contrary to its intended purpose of correcting the inflated markup of AWP. As United States District Judge Saris stated in her order approving the settlement, "AWP has been exposed as a faux inflated price unrelated to actual drug prices... [and]...rolling back AWPs or phasing them out as a pricing benchmark is in the public interest." *New England Carpenters Health Benefit Fund v. First Databank, Inc.*, (D. Mass. March 17, 2009) (order granting final approval of settlement). In addition, the State failed to demonstrate why the increased rate was needed to ensure adequate pharmacy payment given the findings of the Court regarding the AWP inflation in the *First Databank* litigation.

The State failed to demonstrate that the increased payment rate is necessary in order to correct an inadequate EAC, or how access would be adversely affected without the increased rate. The State also failed to present supporting evidence for its method for calculating the increased payment rate or the manner in which this payment is consistent with the current definition of EAC in the regulations presently codified at 42 CFR 447.502. In view of these facts, the State has not provided sufficient evidence to support the proposed payment rate increase. Therefore, I find that the increased payment does not comply with the requirements of section 1902(a)(30)(A) of the Act and Federal regulations defining the EAC.

Based on the above, and after consultation with the Secretary as required by Federal regulations at 42 CFR 430.15(c)(2), I am disapproving South Carolina SPA 10-009. If you are dissatisfied with this determination, you may petition for reconsideration within 60 days after receipt of this letter in accordance with the procedures set forth at 42 CFR 430.18. Your request for consideration may be sent to Ms. Cynthia Hentz, Centers for Medicare & Medicaid Services, Center for Medicaid, CHIP and Survey & Certification, 7500 Security Boulevard, Mail Stop S2-01-01, Baltimore, MD 21244-1850.

If you have any questions or wish to discuss this determination further, please contact Barbara Edwards, Director, Disabled & Elderly Health Programs Group, Centers for Medicare & Medicaid Services, Center for Medicaid, CHIP and Survey & Certification, 7500 Security Boulevard, Mail Stop S2-14-26, Baltimore, MD 21244-1850.

Sincerely,

A handwritten signature in blue ink, appearing to read "Donald M. Berwick", is written over a horizontal line.

Donald M. Berwick, M.D.

From: Melanie Giese
To: Emma Forkner; Jeff Stensland; William Feagin
CC: Jan Polatty; Valeria Williams
Date: 10/12/2010 9:46 AM
Subject: Re: Fwd: SC SPA 10-009

Emma,
It was my understanding from William's email Friday afternoon that we would use the exact statements contained in the forth-coming CMS denial letter as our bullets, particularly since we expect the letter to be FOIA'd.
Please let me know if that is not correct.
BZ

M. Melanie "Bz" Giese, RN
Bureau Director, Health Services
SC DHHS
PO Box 8206
1801 Main Street, J-1224
Columbia, SC 29202
803-898-2868
803-255-8353 (fax)

>>> Emma Forkner 10/12/2010 8:42 AM >>>
BZ, I know it only been a few days but want to make sure we have some bullets forthcoming. The hard copy of the letter will arrive any day & we will need to be ready to discuss. Let me know if I can help you out.

Emma

Emma Forkner
Director
Department of Health and Human Services
1801 Main Street
Columbia, South Carolina 29201
(803) 898-2504
(803) 255-8338 fax

>>> Jeff Stensland 10/8/2010 2:02 PM >>>
That summary would be good to have.

Jeff Stensland
SC DHHS
(803) 898-2584

>>> Emma Forkner 10/8/2010 2:00 PM >>>
fyi on the SPA regarding the AWP changes. I've ask BZ to provide a summary of reasons for the SPA disapproval that we can use to communicate with Legislative Staff and the Pharmacy lobbyist and professional organizations. Until we have that list, I'd ask everyone to keep this information internal. We all need to be using the same speaking points.

CMS did identify a same page issue which BZ says is easy to fix - has to do with listing dates.

Emma

Emma Forkner
Director
Department of Health and Human Services
1801 Main Street
Columbia, South Carolina 29201
(803) 898-2504
(803) 255-8338 fax

>>> "Glaze, Jackie L. (CMS/CMCHO)" <Jackie.Glaze@cms.hhs.gov> 10/8/2010 1:27 PM >>>

Hi Emma:

I want to follow up with you regarding SPA 10-009. I understand that CMS has had pre- and post-SPA submission discussions with the State regarding this SPA and you understand the conditions for the disapproval.. In addition, the State was required by a State Legislative proviso strongly advocated by the pharmacy providers to submit the SPA.

During the review, the NIPPT discovered some same page issues , essentially to add the language to Att. 4.19B, Page 3b, 11a, 11b and 11c that indicates the date the agency set the rates and the fee schedule rates are the same for both governmental and private providers. We would like to work with you on an informal basis to make these revisions, if you are agreeable to do. Please let me know if you have any questions, Thanks, Jackie

Jackie Glaze
Associate Regional Administrator
Atlanta Regional Office
Division of Medicaid and Children's Health
Centers for Medicare & Medicaid Services
Phone: 404-562-7417
Fax: 404-562-7183
Mailto:Jackie.Glaze@cms.hhs.gov (mailto:Jackie.Glaze@cms.hhs.gov)

Brenda James - Denial Letter

From: Melanie Giese
To: Jan Polatty
Date: 10/11/2010 1:39 PM
Subject: Denial Letter
CC: Brenda James

Would you be so kind as to let me know when the denial letter for SPA 10-009 comes in? Many thanks.

M. Melanie "Bz" Giese, RN
Bureau Director, Health Services
SC DHHS
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1801 Main Street, J-1224
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Log # 249

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Ms. Emma Forkner
Director

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Department of Health & Human Services
CENTERS FOR MEDICARE & MEDICAID SERVICES

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I am unable to approve this SPA because it does not comply with section 1902(a)(30)(A) of the Social Security Act (the Act), which requires, in part, that States have methods and procedures in place that payment rates are consistent with efficiency, economy, and quality of care. Under that authority, the Secretary has issued regulations prescribing State rate setting procedures and requirements. Longstanding requirements of Federal regulations presently codified at 42 Code of Federal Regulations (CFR) 447.512 provide that payments for drugs are to be based on the ingredient cost of the drug and a reasonable dispensing fee. States establish their reimbursement methodologies for the ingredient cost of a drug through the EAC. The definition of EAC, presently codified at 42 CFR 447.502 is "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers."

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Donald M. Berwick, M.D.



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