



Administrator

Washington, DC 20201

DEC 01 2010

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

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."

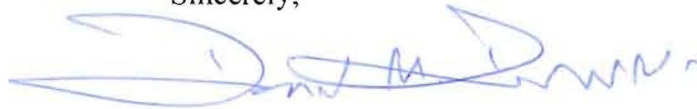
In support of its proposal, the State indicated that it submitted this SPA in response to a State directive contained in the South Carolina 2010-2011 Appropriations Act. The directive requires the State to submit a SPA to CMS by October 31, 2010, that proposes, in part, to increase the EAC from AWP minus 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 AWP's 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", with a stylized flourish at the end.

Donald M. Berwick, M.D.