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 and State Operations

July 6, 2007 **SMDL #07-007**

Dear State Medicaid Director:

Today the final rule to implement the pharmacy provisions of the Deficit Reduction Act of 2005 (DRA) was put on display at the *Federal Register*. The provisions of this rule will take effect on October 1, 2007. This letter highlights the key provisions of the final rule, the time table for its implementation, the actions that States will need to take, and the flexibilities that continue to be available to you. The implementation timeline is enclosed. The final rule is on our Web site at http://www.cms.hhs.gov/MedicaidGenInfo/Downloads/CMS2238FC.pdf.

The DRA changes the requirements for drug manufacturers that participate in the Medicaid Drug Rebate Program. First, it clarifies what drug sales are to be included in average manufacturer price (AMP) and best price. It also provides that customary prompt pay discounts extended to wholesalers be excluded from AMP and that the sale price of authorized generic drugs from the primary manufacturer to a secondary entity be included in the best price of the primary manufacturer's drugs. These changes will cause AMPs to differ from what they were in the past. Best prices of drugs may also be affected by the final rule. This will affect the unit rebate amounts that we provide you for invoicing drug manufacturers for rebates.

The DRA also requires drug manufacturers to report AMPs on a monthly basis. The first monthly AMPs to be calculated under this rule will be for October 2007. Those AMPs will be due from manufacturers by November 30, 2007. The first quarterly AMPs under the new rules will be for the October 2007 – December 2007 quarter. Those AMPs will be due from manufacturers by January 30, 2008.

The new monthly AMPs will be used to calculate the Federal upper limits (FULs) for drugs subject to that limit. We expect to publish the first monthly FULs in late December and apply the aggregate cap on payments for drugs subject to a FUL beginning January 30, 2008.

The DRA also requires that States obtain information on claims for certain physician-administered drugs sufficient to bill drug manufacturers for rebates. Specifically, for Federal financial participation to be available with respect to such physician-administered drugs beginning January 1, 2008, States must obtain National Drug Codes (NDCs) for claims for the top 20 multiple source drugs. These drugs are posted on the Centers for Medicare & Medicaid Services Web site at:
http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Top20PhysicianAdministered.pdf.

Now that the final rule is effective October 1, 2007, we encourage States to begin to consider how to implement these changes. Specifically, you should review your payment amounts for drugs subject to a FUL and determine how you will adjust them, as necessary, to assure that your spending for these drugs, in the aggregate, is at or below the FUL.

You may also consider using the AMP or prices from the Retail Price Survey (which we will send to you in the near future) to revise your payment methodologies for drugs not subject to a FUL. Because the AMPs are based on the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, we believe you will need to apply an appropriate mark-up of these amounts if you are going to use them to set payment rates. Should you decide to change your drug payment methodology, you will need to submit to us a State plan amendment for our approval.

As the acquisition cost of drugs to pharmacies becomes more transparent and better represents actual costs, we encourage you to also review your dispensing fees to ensure that they are reasonable and reflect the cost of dispensing drugs.

The DRA provides that States may seek an extension of the January 1, 2008, deadline for collecting NDCs on claims for the top 20 multiple source physician-administered drugs. Because the DRA was enacted in February 2006, we believe that most States should be able to meet this deadline. However, States that wish to apply for an extension should send me a letter explaining the reason for the extension request, the actions that have been taken to date to meet this requirement, and a specific plan and timeline for coming into compliance with this provision.

We believe that the DRA provides States with an opportunity to establish more appropriate payment policies for prescription drugs. At the same time, we share an interest in making sure that pharmacies receive sufficient payment to continue to serve Medicaid beneficiaries. We look forward to working with you as you implement these new provisions of law.

Sincerely,

/s/

Dennis G. Smith
Director

Enclosure

cc:

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