

# United States Senate

WASHINGTON, DC 20510

March 13, 2007

Leslie V. Norwalk, Esquire  
Acting Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Proposed Regulation Implementing AMP

Dear Acting Administrator Norwalk:

We write to express deep concern that a recently proposed Centers for Medicare and Medicaid Services' (CMS) rule regarding prescription drug pharmacy reimbursement in the Medicaid program will threaten the existence of retail pharmacies and severely restrict the ability of millions of Medicaid beneficiaries to access prescription drugs from pharmacies.

As you are aware, the Deficit Reduction Act of 2005 (DRA) required that CMS post and use average manufacturer price (AMP) data to set reimbursement for generic drugs as a benchmark for states to use in reimbursing retail pharmacies. In the DRA, Congress intended CMS to promulgate a rule that would more clearly define (AMP). In our view, this definition should closely approximate the costs incurred by retail pharmacies to purchase drugs. Rather than providing clarity or an accurate reflection of retail pharmacy drug costs, the proposed rule threatens retail pharmacies and beneficiary access to critical medications. As a consequence, pharmacies that serve Medicaid beneficiaries may be forced to close their doors. This would be especially devastating for rural areas where pharmacies are a vital part of the fragile health care delivery system. If they go out of business, the economy and the health of thousands of residents will suffer.

The proposed rule creates economic hardships for retail pharmacies and threatens beneficiary access to prescription drugs by including in the AMP manufacturers' sales to non-retail pharmacies, such as mail-order sales and pharmacy benefit manager (PBM) rebates. Mail-order facilities, which are almost exclusively operated by PBMs, are extended special drug prices that are not available to the traditional brick and mortar community pharmacies. Similarly, retail community pharmacies do not receive PBM rebates or discounts. Inclusion of these sales and discounts in the calculation of AMP will only serve to reduce pharmacy reimbursement to rates below actual acquisition costs.

The proposed rule also undermines beneficiary access to generic medications from retail pharmacies by basing the Federal Upper Limit (FUL) for generic drugs on 250% of the lowest

AMP for all versions of that generic medication. A recent Government Accountability Office report that analyzed the impact of the proposed FUL formula found that retail pharmacies will be reimbursed, on average, 36 percent lower than the actual cost they incur. The proposed rule, therefore, requires pharmacies to shoulder significant economic losses for participating in the Medicaid program. Clearly, pharmacies cannot be expected to serve Medicaid beneficiaries when it disadvantages them economically. Moreover, the rule creates a disincentive for pharmacies to dispense generic drugs, which save the Medicaid program and beneficiaries significant resources.

Finally, we understand that CMS intends to release AMP data in the next few weeks. As you know, CMS delayed the release of AMP data last July because of inconsistencies and inaccuracies in the manner in which manufacturers calculated AMP. In doing so, CMS acknowledged the significant disruptions in the Medicaid program, pharmacy operations and broader pharmaceutical market that would occur with the release of unreliable AMP data. The release of AMP data in the next few weeks poses the same dangers. Moreover, since CMS will not have published the final rule defining AMP until July 2007, we believe that CMS should again delay the release of AMP data until it completes its rulemaking process and until AMP is calculated based on a uniform and valid definition used by all manufacturers.

The proposed rule will have a devastating impact on retail pharmacies, beneficiary access to critical medications and the Medicaid program. We request that CMS revise the proposed rule to equitably reimburse pharmacies, protect beneficiary access to necessary drugs and create incentives for cost-saving, generic drug usage.


Sincerely,



Ken Salazar  
United States Senator



Pat Roberts  
United States Senator



MB  
Sam Brownback

Tom Harkin  
Ch. B. St.

Michael E. Bishop  
Rep. Tom

Ben Cardin

Byron L. Dorgan

Jack Reed  
Sh. Brown

Kent Conrad

Debbie Stabenow

St. Harkin

Norm Coleman

Susan Collins

Patrick Leahy

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E. Benjamin Johnson

Chuck Scherer

Bill Nelson

Dick Deuch

Robert Mering

Blaugh R. Linsch

Daniel X. Skaka

Ben Sal

Marcel Boyer

Jeff Bond

Craig Thomas

George V. Kenovich

Olympian Jones

Carl

Caryl Hoyer

Bob Carey, Jr.

James M. Chafe

Sally Kamelias

John G. Hatch

Amy Klubner