

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

May 14, 2007

The Honorable Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Ms. Norwalk:

I am writing you today to express what I believe is Congressional intent regarding an important provision of the Deficit Reduction Act of 2005. On December 22, 2006 CMS published a proposed regulation in the *Federal Register* that would provide a regulatory definition of Average Manufacturer Price, as well as implement the new Medicaid Federal upper limit (FUL) program for multiple source drugs.

When the Deficit Reduction Act (DRA) was written, Congress had significant concerns that use of Average Wholesale Price (AWP) in determining the reimbursement for prescription drugs in Medicaid created significant overpayments because AWP did not accurately represent prices paid in the marketplace. The goal of the DRA was to replace AWP with a metric that more accurately represented drug pricing in the retail market. To achieve this goal, Congress changed the statute so that pharmacy reimbursement in Medicaid is now to be based on the Average Manufacturer Price (AMP). In addition, Congress required CMS to issue regulations to resolve ambiguous elements in the calculation of AMP and clarify how it is calculated. While I appreciate the efforts you have made in more clearly defining AMP, I am concerned that one specific inclusion in the new definition of AMP will lead to it becoming another unrealistic metric used for reimbursement in Medicaid.

I am particularly concerned about the inclusion of rebates, discounts and other price concessions paid to pharmacy benefit manufacturers (PBMs) in the computation of AMP. Rebates, discounts and other price concessions paid to PBMs by drug manufacturers are not reflected in the acquisition cost of retail pharmacies. If the pharmacy ultimately is not receiving price concessions reflective of the rebates, discounts, and concessions paid to PBMs and AMP is supposed to be reflective of factors that go into the actual acquisition costs of retail pharmacies, then pharmacies will be reimbursed using a metric that will almost certainly be below their actual acquisition costs for many drugs. If these rebates, discounts, and concessions are included in the

AMP calculation, state payment rates to pharmacies for prescription drugs will continue to be based on inaccurate or misleading data and the federal upper limit on state reimbursement to pharmacies for prescription drugs in Medicaid will once again not realistically represent actual acquisition cost.

For the final rule to remain consistent with congressional intent, CMS should remove PBM rebates from the calculation of the Average Manufacturer Price. Congress devoted significant time and energy to creating a reimbursement for pharmaceuticals in Medicaid reflective of actual acquisition costs. CMS should use the same standard in implementing the law. Inclusion of PBM rebates is not consistent with that standard and I urge you to act accordingly.

I appreciate your consideration and look forward to working with you on issues critical to the health and well being of America.

Sincerely,

A handwritten signature in blue ink that reads "Chuck Grassley". The signature is written in a cursive, flowing style.

Charles E. Grassley
Ranking Member