The Honorable Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Hubert Humphrey Building, Room 314-G
200 Independence Ave., SW
Washington, D.C. 20201

Dear Dr. McClellan:

I am writing to comment on the Physician Fee Schedule Proposed Rule for 2005 (CMS-1429P) and urge you revise the proposed Medicare reimbursement methodology for separately billable drugs and biologics used in dialysis services.

Section 623 of the Medicare Modernization Act (MMA, P.L. 108-173) required the Centers for Medicare and Medicaid Services (CMS) pay these items based on acquisition costs, as determined by the Office of the Inspector General (OIG) through a survey required by the law. The law requires reductions in reimbursement for drugs and biologics to be added into the composite rate and, thus, remain budget neutral. In aggregate, payment to dialysis facilities would neither increase nor decrease.

In May, 2004, the OIG issued a report (OEI-03-04-00120) on the acquisition costs for the 10 most commonly used dialysis drugs. The OIG produced actual acquisition costs for these drugs. There were significant variation between acquisition costs and the manufacturers’ Average Sales Price (ASP) for different drugs, ranging from 11 percent below acquisition costs to 35 percent above acquisition costs. The OIG also reported that small facilities have higher acquisition costs for drugs than large providers and pay, on average, at ASP plus 4 percent for drugs compared to ASP minus 6 for large facilities.

Instead of using acquisition costs as required by the statute, CMS proposed setting the payment for these drugs at ASP minus 3 percent. ASP minus 3 percent represents the average ratio of acquisition costs to ASP across all drugs and facilities. Such a payment methodology runs counter to the clear Congressional intent in designing the payment provision and will result in many small facilities unable to purchase the drugs below the reimbursement rate.

I urge CMS to reimburse drugs and biologics based on the OIG acquisition costs for each drug. Because the survey of acquisition costs is based on 2003 data, I encourage
you to either update the rates based on growth in prescription drug prices or by an actual survey of manufacturers for their 2005 prices.

I appreciate the opportunity to comment on these issues and strongly encourage you to make changes to the proposed rule based on Congressional intent.

Sincerely,

Nancy L. Johnson
Chairman, Subcommittee on Health