October 8, 2004

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW 314-G
Washington, DC 20201

Dear Administrator McClellan:

On behalf of the Congressional Kidney Caucus and concerned colleagues, we would like to express our concern regarding a proposed change in Medicare’s payment policy for dialysis treatments of patients suffering from end stage renal disease (ESRD). The proposed system would reimburse dialysis centers at 3% below the average sales price (ASP) for separately billable drugs and biologics. If implemented, this policy has the potential to negatively impact both the dialysis centers and the patients they serve.

We believe that this new payment method was not what Congress intended in Section 623 of the Medicare Modernization Act (MMA). Congress instructed the Inspector General (IG) of the Department of Health and Human Services to determine the acquisition costs of separately billable drugs and biologics used in dialysis. Congress instructed CMS to then set payment for those drugs and biologics at the acquisition cost of the drug or biologic as determined by the IG. While the IG has determined the acquisition cost of the drugs and biologics, CMS seems to have disregarded the statute by turning to an ASP-based reimbursement system.

The end result of this is a payment rate that does not adequately reimburse centers for the actual cost of erythropoietin, vitamin D therapy, iron, and other drugs they provide to dialysis patients. This concern was also raised in the September 24, 2004 comment letter of the Medicare Payment Advisory Commission:

“While we encourage cost-effectiveness and keeping pressure on drug expenditures, MedPAC is concerned that certain types of facilities may not be able to purchase injectable drugs at prices that are at or below their costs. To maintain beneficiaries’ access, CMS may need to consider setting the payment rate for separately billable drugs at or above the average sales price.” 1

More importantly, by uniformly setting the payment rate at 3% lower than ASP for all drugs and biologics, the proposed payment formula will in fact pay more than average acquisition cost for some items and less than acquisition cost for others. We believe this clearly violates the letter and intent of the MMA.

Many providers in the dialysis industry would be substantially affected by these payment policy changes. In the case of small or independent providers, the Government Accounting Office (GAO) recently reported to Congress that the costs of dialyzing ESRD patients exceeds Medicare’s payments for those services. The report states, “Given the fixed costs a facility incurs in terms of staffing, equipment, supplies, and rent, revenue from the small patient base in these facilities may not be sufficient to meet costs.” If the uniform payment rate of ASP minus 3% is implemented in the final rule, it will be difficult for these already disadvantaged dialysis centers to seek lower acquisition costs because it will result in an even lower ASP in the future. This will jeopardize patient access as these facilities could be forced to make cutbacks or close.

Please follow the directions clearly given by Congress, to set payment rates for these drugs and biologics at their acquisition cost. CMS should use the drug-specific acquisition cost data, updated for inflation, to set payment levels for drugs furnished during 2005 in connection with the provision of dialysis services if separately billed by dialysis providers.

We thank you for your attention to this matter. We will closely follow the development of this important Medicare policy in the coming months.

Sincerely,

Jim McDermott
Co-Chair, Congressional Kidney Caucus

Mark Kirk
Co-Chair, Congressional Kidney Caucus

Charles Rangel

George Nethercutt
Co-Chair, Congressional Diabetes Caucus

Martin Frost

Dave Camp