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September 24, 2004

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Re: File Code CMS-1429-P; Section 623-Payment for Renal Dialysis Services

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule to implement provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that refine the payment method for end-stage renal disease (ESRD) services. We appreciate the efforts of the CMS staff to better administer and improve payment accuracy for ESRD services, particularly considering the competing demands on the agency. We have comments on several of the issues addressed in the proposed rule.

Comment on paying for injectable drugs

The MMA required that CMS pay providers the acquisition cost for drugs and biologicals beginning in January 1, 2005. Currently, both freestanding and hospital-based facilities are paid \$10 per 1,000 units for erythropoietin. For other separately billable injectable drugs, freestanding facilities are paid 95 percent of the average wholesale price while hospital-based facilities are paid reasonable cost.

CMS obtained information about providers' acquisition costs from the first of two reports recently completed by the Inspector General (IG) of the Department of Health and Human Services. The IG found that in 2003, the four largest dialysis chains had drug acquisition costs that were 6 percent lower than the average sales price (ASP) for ten of the top drugs. A sample of the remaining non-chain freestanding facilities had acquisition costs that were 4 percent above the ASP.

Based on the IG's findings, CMS has proposed setting the drug acquisition cost at 3 percent lower than ASP, which represents the overall weighted average cost for both chain and non-chain facilities, in 2005. CMS will update ASP quarterly based on the ASP reported to the agency by drug manufacturers.

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. This would help providers purchase injectable drugs at or below their costs. However, if CMS makes this change, it should be done in a budget-neutral manner when considering all the other refinements to ESRD payment policies required by the MMA.

MedPAC believes that CMS should monitor the average sales price, providers' acquisition cost, and beneficiaries' access to care. If warranted, the agency can adjust the payment rate to more accurately reflect providers' acquisition cost and do so in a budget-neutral manner.

Comments on creating a basic case-mix adjuster

We believe that the proposed method—to adjust for age, gender, and the presence of peripheral vascular disease and AIDS—is a good start. We also support CMS's efforts to continue to conduct research to refine the case-mix adjustment methods. Doing so is consistent with MedPAC's March 2001 recommendation that payment should be adjusted for factors affecting providers' costs.

MedPAC encourages CMS to improve the basic case-mix adjuster to include beneficiaries' weight and height—body mass index (BMI). CMS acknowledges that beneficiaries with high or low BMI are costly to treat. The agency did not include this variable in the basic case-mix adjuster because it is not collected from claims data. Currently, this variable can only be obtained from the Form 2728, which is completed only when patients first get ESRD.

Because BMI is related to providers' costs, as noted by CMS, we urge the agency to include it in the basic case-mix adjuster using the best available data source currently available—the Form 2728. The case-mix adjuster can be refined once this variable is collected more regularly. CMS is considering modifying the claims submitted by dialysis facilities to include BMI and the length of the dialysis session, which other researchers have shown affects providers' costs. Regularly collecting these data elements will enhance Medicare's ability to both pay providers appropriately and assess the quality of care furnished to beneficiaries.

Comments on cost report data

MedPAC is concerned about the limited number of 2002 cost reports for freestanding dialysis facilities available to derive the basic case-mix adjuster. The proposed regulation states the number of available cost reports declined from 3,034 in 2001 to 2,508 in 2002 "because many facilities have not yet submitted cost reports for that year." It is not clear the reasons for the drop-off in the number of 2002 cost reports considering that freestanding dialysis are required to submit their cost reports to CMS's contractors within three months following the close of

their cost reporting period and that failure to do so may result in suspension of payments.^a Having current cost report data is important in the agency's effort to develop a case mix adjuster and MedPAC's effort to assess payment adequacy.

Comments on adjusting for differences in area wage levels

The MMA gave CMS the authority to adjust the payment rates by a geographic index as the Secretary determines to be appropriate. If the Secretary revises the current geographic adjustments to the composite rate, the revised adjustments must be phased in over a period of time. The current adjustment is a blend of two wage indexes, one based on hospital wage data from fiscal year 1986 and the other developed from 1980 hospital wage and employment data from the Bureau of Labor Statistics.

CMS is proposing to take no action at this time to revise the current set of composite rate wage indexes and the urban and rural definitions used to develop them. Rather, CMS is proposing to evaluate any proposals to revise the area definitions and assess the impact of changes in geographical areas on those payment systems that incorporate adjusters for area wage levels among urban and rural locations.

We encourage CMS to assess the impact of these new urban and rural definitions as soon as possible. Given variation in the price of inputs among market areas, accounting for differences in prices is essential to paying accurately in specific market areas. In 2001, MedPAC recommended that the wage index for the composite rate be based on market wage rates for occupations typically used in furnishing dialysis. Another issue for CMS to consider is whether to continue using "floor" and "ceiling" payments, as is done in paying for dialysis. Currently, areas with labor costs less than 90 percent of the national average are raised to the 90 percent level, while those with costs exceeding 130 percent of the national average are lowered to the 130 percent level.

Conclusion

MedPAC appreciates the opportunity to comment on policy proposals introduced by CMS. The Commission also values the willingness of CMS staff to provide relevant data and to consult with us concerning technical policy issues. If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director at (202) 220-3700.

Sincerely,

Glenn M. Hackbarth, J.D.
Chairman

^aCenters for Medicare & Medicaid Services, Department of Health and Human Services. 2004. *Medicare provider reimbursement manual*. Baltimore MD: CMS.