



## THE KIDNEY CARE COUNCIL

### STATEMENT OF THE KIDNEY CARE COUNCIL

#### Regarding the Hearing Entitled:

#### **SAFE AND SENSIBLE: ENSURING KIDNEY PATIENTS RECEIVE SAFE AND APPROPRIATE ANEMIA MANAGEMENT CARE**

#### **Subcommittee on Health of the House Committee on Ways and Means**

**June 26, 2007**

#### **BRIEF OVERVIEW**

The members of The Kidney Care Council (KCC) are dedicated to ensuring high quality patient care. We recognize that Congress, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA) recently have expressed concern regarding the provision of safe and quality dialysis services to End Stage Renal Disease (ESRD) patients. Anemia management is a very complex aspect of caring for patients with kidney failure. In addition, the Medicare Payment Advisory Commission (MedPAC) and the Government Accountability Office (GAO) have spent considerable time examining the Medicare reimbursement of these services in an effort to improve efficiency and assure high quality care in a fiscally responsible manner.

We applaud this attention and are hopeful it will lead to further advances in the remarkable progress America has achieved in the 35 years since ESRD was made a Medicare priority. To ensure continued improvement in patient access to quality kidney care, today's discussion must take into consideration the clinical effect of any policy change on patients, not only on the cost of the drugs. In that regard, the KCC looks forward to working with Congress and the Administration to ensure that ESRD patients receive high quality and safe care under a reimbursement mechanism that appropriately reimburses dialysis providers for high quality care.

#### **THE KIDNEY CARE COUNCIL**

The KCC is a nonprofit health care trade association consisting of eleven renal care companies that collectively provide ESRD services to nearly 80 percent of the dialysis patients in the United States. The membership includes large, small, nonprofit and for-profit provider companies. The KCC's mission is to improve patient care through demonstrable improvements in patient outcomes, safety, and quality of life measures. The KCC is dedicated to improving quality as well as promoting education so that newly diagnosed patients fully understand this disease and how to slow its progression and reduce complications.

KCC members operate freestanding dialysis clinics and hospital-based centers in both urban and rural areas. All of the KCC member companies are committed to working with Congress and the Medicare program to ensure good patient access to high quality dialysis services across the country.

## DISCUSSION

### The Need for Reform

It has been observed that the ESRD payment system is like the 1972 Chevy many Americans once drove. It runs and has some of the basic features of a car. But we wouldn't buy it today for ourselves or our kids to drive. In short, it's in need of an overhaul.

This comes as no surprise. The addition of ESRD services to the Medicare program has saved many thousands of lives. Because of Congress' action in 1972, patients with kidney failure were able to access the life-saving dialysis and transplantation services they needed. Over the course of those 35 years, we have learned much – but that insight has not yet been translated into improvements in how the Medicare ESRD program operates.

There is no question that reforming the ESRD program is a complex task. Thanks to the leadership of lawmakers like Representatives John Lewis and Dave Camp, as well as the nearly 100 Members of the House who have cosponsored the *Kidney Care Quality and Education Act* (H.R. 1193), the subject of ESRD program reform is getting considerable attention. This hearing is a key part of that conversation as it raises important clinical and payment reform questions. It is in the interest of aiding and participating in this dialogue and seeking sustainable, patient-focused reform that we respectfully offer the following perspectives.

### Anemia Management

Simply put, patients with ESRD do not have adequate erythropoietin of their own, and without exogenous ESA products, these patients become profoundly anemic and require frequent blood transfusions. As such, anemia management is a critical and complex component of caring for dialysis patients. Effective management using erythropoietin stimulating agents (ESAs) is the standard of care in the dialysis population. Effective management improves patient quality of care and quality of life for more than 400,000 Americans living with Stage 5, or end-stage, chronic kidney disease. As such, ESAs are an indispensable, permanent component of a patient's therapy and have a long track record of safety and efficacy.

Quality of care is judged by meeting CMS' ESRD Clinical Performance Measure (CPM) targets. Sixteen CPMs, based on the National Kidney Foundation's Kidney Disease Quality Initiative Clinical Practice Guidelines, were developed in 1998 to measure and report the quality of dialysis services with regard to adequacy of hemodialysis and peritoneal dialysis, anemia management, and vascular access management. In terms of

measuring the anemia status of a dialysis patient, the CPMs call for hemoglobin levels for all ESRD patients to be maintained above 11 g/dl. This level dramatically improves the lives of ESRD patients, and is associated with reduced hospitalizations and reduced mortality rates.

While dialysis facilities administer ESAs and provide constant monitoring of their impact on patients, it must be underscored that facilities do not prescribe ESAs. Nephrologists, the attending physicians who oversee the treatment of ESRD patients, and their Nurse Practitioner and Physician Assistant colleagues, are the only individuals who under law order ESAs for their patients. As such, dialysis providers do not have control of the amount of ESAs administered in their facilities.

### Patient Variability

It is important to note that patients respond differently to the treatment of anemia. Apart from maintaining adequate iron and mineral stores to ensure their function, the most important determinants of response to ESAs are the clinical events a patient encounters during the year. A variable baseline and ongoing response to ESAs exists among patients, the response for each patient over the year is unique because the clinical course of each patient *through* that year is uniquely his or hers. During the course of a year, a patient may develop a variety of difficulties or other clinical events (e.g., illnesses such as pneumonia, malignancies, vascular access problems, other infections, admissions to the hospital, minor or major surgical problems) which all impair response to ESAs. Fortunately, the negative impact of these difficulties is usually reversible.

Any of these problems may alter profoundly the required dose of an ESA to maintain hemoglobin, requiring significant adjustments in dose for weeks or months until the problem resolves. A simple analogy is appropriate: using ESAs to keep a patient within a targeted hemoglobin range is akin to an airplane crossing the country needing to maintain steady speed. More fuel is required to maintain that speed in the presence of headwinds than in clear air; and the headwinds are sporadic and unpredictable. Since most patients encounter widely fluctuating doses of ESAs during the year due to such clinical events, it follows that discussion about ESA dosing must consider patients on an individual basis.

Some segments of ESRD patients have an intrinsically low response rate to anemia management therapy, and, therefore, require higher doses of ESAs to achieve clinical performance targets. For example, the particular clinical needs of certain patient groups, such as African Americans, can require higher levels of ESAs in order to generate red blood cell development. In fact, there is concern based on available evidence that African Americans might be disproportionately affected by decisions that curtail use of ESAs.

One difficulty clinicians face in anemia management is that the impact of a change in ESA dosage may take approximately two weeks – sometime more – to be observed. ESAs are quite different from insulin in that respect, as the responses to dosage changes of insulin for patients who require it are observed rather quickly. Appropriate ESA

dosing is hampered by the clinical reality that the effect of dose change is poorly predictable in the ensuing weeks or months.

Patients, unfortunately, do not always remain within targeted hemoglobin ranges for many of the reasons noted above. Lacson et al, in a study of 70,000 patients found a patient's clinical picture can vary dramatically within a single year, thus requiring constant titration of ESA doses.<sup>1</sup> Nearly one third of patients starting the year in the highest hemoglobin category were, by the end of the year, in the lowest hemoglobin category. Similarly, nearly one third of patients in the lowest hemoglobin category by the end of the year, were in the highest hemoglobin category. Effective care, thus, requires the individualization of ESA therapy.

As difficult as it is to maintain hemoglobin levels, members of the KCC have protocols in place that require providers to reduce ESA dosing when patients either reach or exceed 13 g/dL. Indeed, an estimated 85 percent of patients resume a sub-13 g/dL level within three months and all patients are below 13 g/dL within six months.

### Safeguards Needed

Perhaps the greatest potential risk in the debate over ESA dosing is ineffective care in the form of under-utilization of ESAs. In their recent analysis of hemoglobin outcomes, Lacson et al noted the broad, bell-shaped distribution of patients and their hemoglobin levels.<sup>2</sup> In this paper, the authors projected what could happen when efforts are made to decrease the number of patients with low hemoglobins in large populations (consistent with the quality expectations established by CMS): that is, the number of patients exceeding the upper hemoglobin limit increases.<sup>3</sup> Conversely, as one attempts to lower the upper hemoglobin limit across the dialysis patient population, one increases the proportion of patients in the sub-11 g/dL range.<sup>4</sup> Patients in this range (sub-11 g/dL) of anemia management have a greater propensity for hospitalization and increased mortality.

While the KCC members fully support the CMS National Monitoring Policy for EPO and Aranesp, the policy has had both positive and negative effects. Ofsthun and Lazarus found that while the EPO monitoring policy appears to have reduced slightly the percentage of patients with a hemoglobin level of greater than 13 g/dl, it also has increased the percentage of patients with levels in the medically undesirable range of less than 11 g/dL.<sup>5</sup> This critical observation about how ESAs work in humans underscores an important unanticipated negative effect of regulation.

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<sup>1</sup> Lacson E, Ofsthun N, Lazarus JM. Effect of Variability in Anemia Management on Hemoglobin Outcomes in ESRD, *Am J Kidney Dis* 2003; 41:111-124.

<sup>2</sup> Lacson, E, *supra* note 1.

<sup>3</sup> *Id.*

<sup>4</sup> Ofsthun, N, Lazarus, JM. Impact of the Change in CMS Billing Rules for Erythropoietin on Hemoglobin Outcomes in Dialysis Patients, *Blood Purif* 2007; 25:31-35.

<sup>5</sup> *Id.*

## Payment Reform

A number of proposals for reform have been discussed including broadening the current ESRD composite rate – the “payment bundle” – as well as drug reimbursement reform. At present, Medicare pays facilities for most dialysis services using a bundled approach. Routine costs for supplies, equipment, space, professional, clinical, and clerical staff, some laboratory tests and some drugs are paid by a per-treatment prospective bundled payment amount. This rate varies to reflect the average acuity (or “case mix”) of patients served in each facility and is adjusted across the country to reflect cost-of-living differences. In 2007, the base composite rate for free-standing facilities is approximately \$133.<sup>6</sup> The drug add-on payment is approximately \$20. Under current law, certain drugs and clinical laboratory tests are excluded from the composite rate and paid separately.

The cost of treating Medicare beneficiaries with ESRD has been rising at a rate far above the Medicare reimbursement for dialysis services. Dialysis providers have experienced substantial increases in all labor costs. In spite of the stagnant payment rate, providers have experienced increases in all components of providing care, especially with respect to modernizing equipment and facilities.

In fact, the composite rate for dialysis services does not receive an annual inflation update. While other health care providers have received steady up-ticks in their payments year over year, dialysis providers are losing ground. From 1990 through 2006, the Consumer Price Index (CPI) for medical products and services (CPI-M) increased by 111 percent, the general CPI by 54 percent, and hospital payments by 36.1 percent. Over the same time period, Medicare payment to dialysis providers increased by only 6.8 percent.

While this lack of a permanent update mechanism has resulted in Medicare payments that do not cover patient treatment costs, dialysis providers have continued to provide high quality health care to Medicare beneficiaries. The members of the KCC have accomplished this, despite the Medicare reimbursement shortfall, by cross-subsidizing Medicare reimbursement with the higher rates from private insurance. However, this system is simply *not sustainable* for the future, as the numbers of private pay patients decline and as dialysis providers compete with other health care providers for qualified staff. Comprehensive and balanced reform is needed to ensure that Medicare reimbursement keeps pace with treatment costs while preserving patient access to high quality care.

As noted by some in Congress, CMS, MedPAC, and GAO, an expanded payment bundle would improve efficiency and clinical flexibility for the provision of ESRD services. The Medicare Modernization Act of 2003 (MMA) requires CMS to design a modified system that would no longer pay for each injectable ESRD drug under a separate rate, but would bundle payment for these drugs together with other ESRD items and services under a single rate. The MMA also mandated a demonstration testing the feasibility of such a system. Both CMS’ design report and the demonstration are delayed.

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<sup>6</sup> Hospital-based facilities are paid an average of about \$4 more than free-standing facilities.

## KCC Support

Recognizing Congressional interest in the Medicare ESRD payment program, the KCC offers its support of comprehensive reform to improve efficiency and assure continued high quality care in a fiscally responsible manner.

The KCC members strongly believe that any reformed payment methodology should establish an annual reimbursement update mechanism that incorporates quality achievement and improvement. The payment system for dialysis services is the only Medicare prospective payment system for which the law provides no automatic annual update to reflect the increasing costs of providing services.

With respect to expanding the current bundled payment, the expanded bundle should include those items and services that are already included in the composite rate and those items and services that are routinely provided to ESRD beneficiaries during the provision of dialysis care. More specifically, designated drugs that are regularly administered in the dialysis unit should be included in the bundle.

Other drugs, however, such as ESAs, deserve special consideration. As mentioned, ESAs are widely recognized as the standard of care for the treatment of anemia in ESRD patients. Providers of dialysis services, however, are vulnerable to the continuously rising costs of ESAs because of a unique monopoly that has resulted from a single seller of ESAs in the dialysis market. The lack of competition for such critical pharmaceutical products for ESRD patients has a considerable impact on provider reimbursement and, ultimately, for beneficiaries due to the escalating costs of the product. Epogen, for example, represents 25 percent of Medicare's costs of dialysis services for ESRD patients. As a result, the success of any policy that expands the composite rate bundle will depend critically on provisions to protect providers from significant increases in the prices of ESAs. Organizations that operate a small number of dialysis facilities lack economies of scale in providing dialysis care, and are particularly challenged in the acquisition of drugs and laboratory services.

Finally, KCC is supportive of efforts to ensure that ESRD beneficiaries continue to have access to and are provided high quality dialysis services. We are ready for pay-for-performance, especially a system that rewards providers who meet predetermined clinical standards or produce positive improvements in patient clinical outcomes, which ideally would be tied to an annual payment updating mechanism (as is done in other Medicare provider segments). We have already achieved the quality outcomes that are the foundation of any pay-for-performance system. In addition, the Kidney Care Partners (KCP) – an alliance of the broader kidney care community – is preparing for additional quality advances in the near future by mapping an ambitious quality improvement agenda, the Kidney Care Quality Initiative (KCQI). The KCQI is charged with developing a consensus-based pay-for-performance program that includes clinical and quality of life measures and takes into account the unique needs of pediatric patients. The KCQI's goal is to develop a program that federal policymakers can implement immediately. We believe this program is ready for consideration now, and we are fully

supportive of the efforts of this Committee and other Federal policymakers to inject value-based purchasing models into the Medicare ESRD program and into Medicare's other payment systems.

We are confident that through such reform, our objectives to preserve patient access to high quality care and create an ESRD payment system that will adequately reimburse dialysis providers for providing such care can be accomplished.

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