



December 16, 2009

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

**Re: CMS-1418-P; Medicare Programs; End-Stage Renal Disease Prospective Payment System; Proposed Rule**

Dear Ms. Frizzera,

On behalf of our 1,000 physician members, The American Nephrology Council (ANC) appreciates this opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the Prospective Payment System (PPS) for Medicare ESRD Beneficiaries. ANC believes that it was a proper decision that physician reimbursement not be included within the PPS, but we are concerned about the potential impact the PPS could have on dialysis patients and the limits that could be placed on nephrologists.

ANC is a national, not-for-profit organization of nephrologists seeking to advance the common interests of kidney patients, nephrologists and dialysis providers. ANC is dedicated to increasing the number of doctors actively engaged in kidney care advocacy and promoting appropriate federal and state payment policies to allow for the continued advancement of quality patient care.

For the past few years, ANC has been working to heighten awareness of issues that may affect kidney patients, nephrologists, and dialysis providers, in order to form a strong and more unified "voice" to promote responsible public policy on behalf of the kidney care community. We strive to work cooperatively with other patient, physician and provider organizations to advance our common goals in the delivery of quality care.

**Other Drugs and Biologicals and their Oral Equivalents**

ANC believes that nephrologists should have the opportunity to treat their patients to the best of their ability, in accordance with the best evidence-based medical practice. Nephrologists currently have the ability to treat each patient as an individual. This includes prescribing the treatments that are most beneficial to the patient, as well as prescribing the medications that will best manage their particular conditions. We are concerned that the current proposed ESRD PPS bundling of oral medications with no injectable equivalents will undermine this goal.



The care of dialysis patients is quite complex and medication regimens vary widely among patients. For example, the management of multiple metabolic derangements commonly found in these patients requires close monitoring of laboratory studies, with frequent adjustment of medications. The bundling of these medications may have significant negative impact upon the availability, delivery and ultimately the appropriate and necessary administration of these medications to these highly vulnerable patients. At this time, many patients obtain these medications through their private insurance benefits or Medicare Part D. It is of great concern to the ANC that bundling of these medications, without proper funding, will lead to decreased patient access to them, with a decline in the quality of clinical outcomes.

### **Availability**

As structured, the proposed ESRD PPS allots only approximately \$14 per treatment for oral medications.<sup>1</sup> This is far less than the anticipated cost of between \$45 and \$100 per treatment for the actual cost of providing these drugs. We are very concerned about how the underfunding of oral medications will limit nephrologists' ability to treat each patient individually in a manner designed to achieve optimum outcomes. The current proposal for funding of these medications is unrealistic and will render adequate maintenance of bone and mineral health fiscally impossible.

Due to the high costs of non-generic medications, drug formularies could be put into place to manage costs. However these formularies could dictate the use of medications which are the least expensive for a given indication, regardless of clinical efficacy. Not only could this result in many dialysis patients receiving non-optimal treatment, but it would hamper the nephrologists' ability to treat each patient as needed to meet standards within KDOQI guidelines.

**Patients and nephrologists should not be forced to accept poor clinical outcomes due to this funding issue. CMS should either exclude oral medications from the PPS or provide full and accurate funding of these medications so that nephrologists have the ability to prescribe the medications that are most appropriate and effective for their patients.**

### **Innovation**

The current PPS does not have a mechanism to encourage pharmaceutical innovation and the development of new medications. If only \$14 per treatment is included for oral medications, there is little incentive for pharmaceutical companies to engage in the costly research and development necessary to bring new medications to the market. Nephrologists will have fewer new tools with which to treat patients, and patients will cease to see advancements in medical treatments which could improve their quality of life or quality of care.

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<sup>1</sup> Proposed Rule page 2.



**ANC believes CMS must articulate how the costs of new medications will be addressed within the ESRD PPS to ensure that nephrologists have the freedom to prescribe, patients to receive and facilities to be reimbursed for new and innovative medications that could improve patients' quality of life and outcomes.**

## **Diagnostic Laboratory Tests**

### **Differentiation of Laboratory Studies**

In the proposed ESRD PPS, there is not a clear differentiation of specific laboratory studies that will be covered in the payment to the dialysis facility. Nephrologists want to ensure that patients receive all necessary laboratory testing, which provides crucial data to the physician on how to properly treat each patient's condition. Limiting the ability of physicians to order the necessary laboratory studies required by the individual patient's clinical indications may result in less coordination of laboratory utilization, increased duplication of studies, increased phlebotomy, and less efficient reporting of results.

**CMS should create a clearly defined list of ESRD-related laboratory studies that will be included within the PPS. In addition, CMS must make provisions for additional testing to be drawn in the dialysis facility and separately billed when deemed clinically necessary by the physician. This will reduce patients' travel, minimize phlebotomy, and allow for more efficient reporting of and responding to clinical results.**

## **Self Dialysis Training**

### **Home Dialysis Training**

ANC supports patients having education about and access to all dialysis treatment options including home dialysis. As a result, ANC was pleased that the proposed PPS included provisions designed to allow patients the opportunity to utilize home dialysis options. Specifically, ANC was pleased to see that modalities were valued equally—providing an equal reimbursement rate for peritoneal dialysis (PD) as other modalities.

ANC was also pleased with CMS's response to the Government Accounting Agency's (GAO) Study on Home Dialysis. The GAO recommended that CMS establish and implement a formal plan to monitor the expanded bundled payment system's effects on home dialysis utilization rates. In its response CMS stated that it intends to address the affects of the expanded bundle on home dialysis utilization following the formal comment period and promulgation of the final PPS rule.<sup>2</sup>

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<sup>2</sup> End-Stage Renal Disease: CMS Should Monitor Effect of Bundled Payment on Home Dialysis Utilization Rates. GAO-09-537, May 22 2009.



While ANC is encouraged by CMS's stated goal of encouraging home dialysis, we are concerned with other areas of the proposed PPS as they relate to home dialysis. Currently, the costs of providing home dialysis training are outside the composite rate. Facilities receive an additional payment for providing home training. While the current training reimbursement does not cover the true cost of providing the services, it does provide an additional incentive for dialysis facilities to provide the service. The proposed PPS's spreading of the training costs across all patients would not provide a direct incentive for facilities to provide training.

While the proposed PPS does provide for a new patient adjustor for the first 120 days, many patients do not undergo home dialysis training during this time, since most nephrologists are working to stabilize their patients and determine the proper prescription for dialysis. Patients tend to enter home dialysis training programs following the first 120 days of treatment. In addition, since patients under 65 years of age do not become Medicare eligible until after the first 90 days, most patients would only be eligible for a 30 day adjustor instead of the full 120 day adjustor. Thus, the adjustor would not adequately apply to home training. This adjustor would also not take into account individuals who change modalities.

**ANC encourages CMS to continue to reimburse PD equally as compared to other modalities. In addition, ANC encourages CMS to monitor the effects of the PPS on home dialysis utilization. ANC also recommends that CMS provide a payment for those patients undergoing home dialysis training. This payment would not only provide an incentive for facilities to provide home dialysis as an option, but would allow nephrologists the freedom to prescribe the treatment option best for the patient with confidence that the modality will be available.**

### **Unit of Payment**

ANC was pleased with many of the provisions included in the PPS. CMS's decision to exclude physician fees from the PPS has been a beneficial step for both nephrologists and our patients. Excluded nephrologists payments will continue to provide nephrologists with the flexibility to treat our patients in the manner we deem best. Specifically, nephrologists will have the ability to round on and examine patients in the manner dictated by clinical status. For our patients, it will mean there will not be a financial disincentive for frequent evaluation by their nephrologist.

Because dialysis facilities are reimbursed for each dialysis treatment, many dialysis patients are able to travel. If the PPS had been structured based upon weekly or monthly reimbursement, it would have created a very difficult situation for facilities trying to determine how to obtain reimbursement for transient patients, resulting in many facilities refusing to accept them. A patient having the ability to travel and maintain as rich and normal a life as possible is essential to their mental and physical health.



In addition, CMS's allowing for medical justification of additional dialysis treatments is vital to the nephrologist's ability to treat patients optimally. Without the reimbursement for additional treatments with medical justification, nephrologists would not be able to treat patients with excessive fluid gains between routine treatments, acute electrolyte perturbations, or other potential problems as they arise. Failure to allow for additional treatments when medically necessary would result in increased hospitalization, more frequent clinical complications for patients, and overall increases in expenditures to treat problems which could have been prevented with additional outpatient dialysis.

Similarly, medical justification allows for dialysis facilities to receive additional reimbursement for providing more frequent dialysis. Numerous studies have shown the benefits of more frequent dialysis—whether it is peritoneal dialysis or home hemodialysis. Ultimately, medical justification for additional treatments will allow nephrologists to prescribe home dialysis for those patients for whom it is the optimal therapy.

**ANC requests that CMS continue to exclude nephrologist payments from the PPS and retain the per treatment reimbursement and medical justification for additional treatments in the final ESRD PPS.**

### **Proposed Patient Level Adjustment**

#### **Adjustor for Race**

Many of the adjustors placed in the PPS are designed to ensure that all patients have equal access to treatment regardless of co-morbid conditions. This ensures patients with more medically complex conditions are afforded the same access to care as other less costly patients.<sup>3</sup> Specifically, African-Americans tend to require additional care and medications as compared to other patients. It is troubling that CMS has admitted that race factors into higher dialysis costs but did not include it as one of the adjustors. Without an adjustor for race, many nephrologists and dialysis facilities will be limited in their ability to prescribe appropriate treatment and thus, unable to properly treat patients who lie outside the “bell curve” with regard to their anemia management or other conditions. This could result in inadequate treatment of minority patients or a reduction in the access to care to care for patients in predominantly minority areas.

**If CMS is to propose patient adjustors for the ESRD PPS, a race adjustor should be included and take into account the increased costs of treating African-American and other racial and ethnic minority patients and ensure that the cost of treating a patient does not factor negatively in that patient's access to dialysis care.**

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<sup>3</sup> Proposed rule page 27



## Quality Incentive Program

The Quality Incentive Program (QIP) being developed by CMS will be an important step toward improving the quality of dialysis care by reducing mortality and bettering patient outcomes. ANC commends CMS on the QIP and would like to provide input on a few of the potential measures.

### Anemia

Per MIPPA and the FDA Label on ESA's, a patient's hemoglobin should be kept between 10g/dl and 12g/dl. If the hemoglobin falls below 10g/dl or rises above 12g/dl, CMS proposes to reduce the PPS payment. This inclusion of ESA within the PPS will ensure that ESA's are not over utilized and that appropriate dosing of these costly agents is maintained. ANC's concern is that the bundling of ESAs already poses a financial disincentive to adequate ESA use, and the threat of an additional disincentive for "overshoot" will lead to maintenance of hemoglobins at the lowest level possible. This may result in significantly worse outcomes for the patient.

**ANC believes that CMS should continue to establish a quality measure for hemoglobins below 10g/dl. However, ANC feels CMS should revise the quality measure for hemoglobins above 12g/dl, allowing for the development of appropriate protocols which will lead to proper utilization of ESAs to achieve the best patient outcomes. Persistently elevated hemoglobin levels should not be permitted, but neither must a disincentive exist for adequate anemia therapy.**

ANC is grateful that CMS has thus far provided nephrologists with the flexibility to treat our patients as we feel is best for their care. We feel many of the provisions stated in the PPS could be beneficial for patient care if properly structured and funded. There are many areas of the PPS that ANC feels CMS must reassess and revise to ensure that nephrologists and other health care professionals may provide the best patient care possible. We thank you for the consideration you have given to this process. We look forward to the final rule and hope that it will incorporate many of our recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Mahoney", is written over a light blue horizontal line.

David L. Mahoney, MD  
President