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 (ESRD PPS) Proposed Rule

Dear Ms. Frizzera:

The American Nephrology Nurses’ Association (ANNA) is pleased to comment on the proposed rule CMS-1418-P: Medicare Programs; End Stage Renal Disease Prospective Payment System (ESRD PPS) published in the Federal Register on September 29, 2009.

ANNA is a professional organization of more than 12,000 registered nurses specializing in nephrology. ANNA develops and updates standards of patient care, educates its practitioners, stimulates and supports research, disseminates new ideas throughout the field, promotes interdisciplinary communication and cooperation, and monitors and addresses issues encompassing the practice of nephrology nursing.

ANNA members work in a variety of clinical environments related to the care of individuals with chronic kidney disease (CKD), but the majority of our members (73%) work in dialysis settings. As reimbursement is a major determinant of how care is organized and delivered, we recognize that the massive changes legislated in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) as proposed to be implemented in this rule will have a major impact on our clinical practice environment, on our practice, and on the patients we treat for years to come.

ANNA is a member of Kidney Care Partners (KCP), a broad alliance of members of the kidney care community. As an active and contributing member of KCP, ANNA endorses the comprehensive comments submitted by KCP on the proposed rule. Our comments in this letter, however, serve to express our thoughts on the rule.
specifically from the nursing perspective. Nurses working in dialysis settings provide direct care to

and spend more time with patients on dialysis than any other group that will be commenting on this rule. As such, we have an important and unique perspective on aspects of the rule that we hope the Agency will carefully consider.

We want to begin by applauding the Center for Medicare and Medicaid Services (CMS) for maintaining the per-treatment unit of payment. This will enable patients to move among providers and facilities without causing administrative burdens to either and will also maintain the focus of all concerned on the importance of each treatment to the patients.

**Bundling of Oral Drugs without an Injectable Equivalent**

ANNA is concerned about the CMS proposal to include oral drugs without an injectable equivalent in the payment bundle, and cannot support it unless, and until, this new Part B benefit for all dialysis beneficiaries is fully funded. The current proposal would cause significant unintended consequences for Medicare beneficiaries. As the federal stewards of the Medicare program, and hence the Medicare beneficiaries, we do not believe that is the outcome the Agency seeks and we are counting on CMS to either fund this benefit properly or implement it at another time.

**Adequacy of Reimbursement**

The current dialysis payment, known as the composite rate, was implemented in 1983. Since that time, nurses in dialysis settings have had to continually “do more with less.” We recognize that prospective payment systems provide opportunities for providers and facilities to reorganize care delivery in ways that are both cost effective and capable of improving quality, and we look forward to working toward those ends. However, the role of professional nursing care cannot be overlooked in that process.

We have concerns that many of the proposals, specifically those related to risk adjustment, outlier payments and low volume facilities have the potential to reduce the average per-treatment payment by more than the two percent legislated in MIPPA. We urge CMS to implement the rule in ways that protect the base rate such that high quality care, which includes access to professional nurses, can be delivered and is not threatened.

We are aware that Medicare reimbursement does not cover the costs of providing care to dialysis beneficiaries. In addition, some 40 percent of Medicare dialysis
patients are also dually eligible for Medicaid. Under many states’ Medicaid plans, providers and facilities do not receive the full 20 percent coinsurance. This reality must also be taken into account as CMS determines policies that affect the average per treatment payment.

**Diagnostic Laboratory Tests**

Expecting dialysis providers and facilities to cover the cost of all lab tests that are ordered by MCP physicians is inappropriate and based on a faulty assumption that “ordered by an MCP” means “required for the treatment of ESRD.” Many of our members are advanced nurse practitioners (NPs) working in nephrology medical practices. Due to their frequent contact with their patients on dialysis, nephrologists and NPs receiving the monthly capitation payment order lab tests that are not related to ESRD or dialysis therapy. Again, out of concern for an appropriate and adequate base rate, we agree with our colleagues that a specific list of ESRD-related lab tests in the ESRD PPS would be a wiser way to approach the implementation of the PPS and a more accurate way of determining the requisite reimbursement to cover the costs of those tests in the PPS payment.

**Case-Mix Adjustors**

ANNA supports the continued use of the existing case-mix adjustors and the implementation of new adjustors for patient race and sex. While we do not believe that females are more costly to treat, it is at least a variable that is known and can be billed.

With regard to race, it has long been observed by clinicians, including nurses, and documented in medical literature that African Americans require higher doses of erythropoietin stimulating agents to achieve the same clinical endpoints as patients of other races. We note that the impact table in the proposed rule shows a larger negative impact of the ESRD PPS on providers and facilities in parts of the country that treat higher percentages of African American beneficiaries, and we believe this impact could rightfully be ameliorated by the use of a race adjustor.

With regard to the broader list of proposed adjustors, we are aware of the difficulty in obtaining medical records for patients who have been hospitalized or treated by other providers. Our concern is that much of the information that would permit billing of the suggested comorbidities is not and would not be available to dialysis providers or facilities. That, combined with the negative impact on the per treatment rate if adjustors cannot be billed to the extent CMS has assumed, will likely leave nurses spending more time requesting and combing through medical records looking for evidence of comorbidities than they would spend treating or educating patients.
We have significant concerns about the first 120-day adjustor. First we want to point out that the majority of patients do not begin home dialysis training in the first 120 days. Evidence of that should be available to CMS since patients who begin dialysis before age 65 are not entitled to Medicare for the first 90 days of dialysis treatment unless they are transplanted or begin a course of self dialysis training. We have many concerns about this particular adjustor because of its financial significance. Primarily, we believe it could lead to patients under age 65 being started on a course of home therapy, most likely peritoneal dialysis, during the first 90 days to trigger the earlier entitlement to Medicare and the higher per treatment reimbursement. CMS should consider the increased costs to the Medicare program of patients becoming beneficiaries sooner than they otherwise would have if this adjustor is implemented.

Home Dialysis

We believe there are incentives for home dialysis in the proposed rule, given the per treatment payment and the consistent payment across modalities. Patients who dialyze at home are known to be hospitalized less frequently and to have lower utilization of medications. Peritoneal dialysis training costs will be recovered in a short period of time under the proposed PPS, but such is not the case for the much more complicated home hemodialysis training. Nonetheless, once patients are on home therapy they cost less to treat and training costs can be recovered over time. The critical point will be the length of that recovery period.

We can envision changes in how patients are trained that would be more efficient and reduce the cost of training, and such changes may indeed come to pass under the PPS. In any case, we are aware of the GAO report earlier this year on home dialysis and CMS’ commitment to monitor the utilization of home dialysis after the PPS is implemented. We believe such monitoring will be necessary to evaluate the impact of the PPS on this form of therapy.

Quality Incentive Program

ANNA has a long history of active involvement in quality improvement activities geared towards improving patient outcomes. Because of this, ANNA fully endorses KCP’s comments on CMS’ early conceptual model for the QIP program, particularly the request to adopt vascular access as a third measure for the initial year of the QIP for hemodialysis patients and the need to develop a more robust QIP as quickly as possible. ANNA looks forward to working with CMS to develop additional measures and to ensure success of the QIP program.

Pediatrics
ANNA recommends that CMS develop a single case-mix adjustor for pediatric patients.

Thank you for your work in preparing this important proposed rule. ANNA looks forward to continuing to work with the Agency as the ESRD PPS is implemented. Please do not hesitate to contact me directly if ANNA can be of assistance.

Sincerely,

[Signature]

Donna Bednarski, MSN, RN, ANP-BC, CNN, CNP
National President