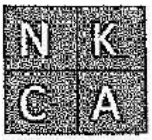

Nonprofit Kidney Care Alliance

August 30, 2013

The Honorable Marilyn B. Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave., SW
Washington, D.C. 20201

RE: CMS 1526-P: Medicare Program End-Stage Renal Disease Prospective Payment System

Dear Administrator Tavenner:

The Nonprofit Kidney Care Alliance (NKCA) represents four nonprofit dialysis providers: Centers for Dialysis Care; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; and Northwest Kidney Centers. Collectively, we serve over 17,500 patients at more than 250 facilities in 29 states. As nonprofit providers, we receive approximately 85% of our payments from Medicare. Our goal is to provide the best service possible for patients on dialysis and to improve care for all patients with kidney disease, including those not on dialysis, thereby decreasing the number of patients needing dialysis and increasing the number who can benefit from a kidney transplant.

The end-stage renal disease (ESRD) PPS bundle has allowed us to innovate to provide better care to our patients while achieving efficiencies in our delivery of care. The bundle has also removed incentives that were not aligned with patient care, such as financial incentives to overuse separately billable medications. We recognize that the decrease in drug utilization, particularly erythropoiesis-stimulating agents (ESAs), should be factored into the payment rate, but the proposed reduction is too steep. If implemented, it will result in real hardship for patients, as some providers—notably smaller nonprofits—will no longer be able to serve their patients.

Effect on Nonprofit Dialysis Providers

The Centers for Medicare and Medicaid Services (CMS) proposed reduction of $29 per treatment poses a risk for smaller and nonprofit providers. We are particularly concerned about the effect of the Proposed Rule on small providers. In its March 2012 report, MedPAC estimated that small dialysis providers have Medicare margins of 0.1%. With Medicaid payments even more limited than Medicare and limited commercial payer reimbursement, the proposed rebasing will create more stress on small providers who are less able to spread the risk.

Smaller providers do not have the opportunity to receive the same discounts as larger providers and do not have the economies of scale of larger providers. As a result, many small and/or nonprofit providers may find that they can no longer care for their patients. Small providers are often the only providers of essential services in isolated areas. We are concerned that these services to patients in remote communities may no longer be available if small providers are unable to operate. We ask that CMS evaluate the rule with its effect on small dialysis providers and their patients in mind.

ESRD Bundle Rebasing Overview

Section 632 of the American Taxpayer Relief Act (ATRA) requires CMS to rebase the ESRD bundle. We believe that any evaluation of appropriate reimbursement should look at the system in its entirety, using the most current data. Indeed, according to the GAO report to Congress that served in part as the basis for the ATRA provision:

> KCC and NRAA also noted that rebasing the ESRD payment rate should take account of more than the utilization of injectable drugs. We do not disagree with this point, but did not address other factors that might be considered in rebasing because our mandate from Congress was to examine injectable drugs. We would expect CMS to consider utilization and other factors in rebasing.

In implementing Section 632 of ATRA, CMS also has responsibility to assure that beneficiaries' access to care under Title XVIII is not compromised. We believe that there are a number of factors that CMS should weigh in reaching a conclusion about the overall net reduction in the single payment for renal dialysis services. For example, when Congress enacted the ESRD PPS bundle, it included an initial 2% payment "haircut." We request that CMS take into account that this adjustment removed approximately $5 per treatment from the base rate for dialysis services.

Comments Regarding Specific Aspects of the ESRD PPS Proposed Rule

Due to the large risk to providers and patients of the proposed $29 reduction per treatment, below we outline specific areas that CMS should carefully consider when promulgating the Final Rule. We believe that proper consideration of these factors will result in a more appropriate rebasing and less detrimental bundle amount. In addition, we offer comments regarding home dialysis and respond to CMS's request for comment regarding a phase-in of the rebasing.

1. **Consider a Different Process When Calculating Change in Utilization**

We support the recommendation from Kidney Care Council (KCC) that CMS follow the process recommended by the Moran Company when calculating the change in utilization. Moran's analysis using data from 2011 finds that the proposed reduction would be significantly less than that proposed by CMS.

2. Properly Consider Cost Data on ESAs

While ESA utilization has declined since enactment of the ESRD bundle, the price of ESAs for small and medium providers has increased. Some of these increases are not yet fully reflected in the average sales price (ASP) data, due to the normal lag in reporting and publishing of these data. We urge CMS to accept data from independent sources in the interim and take the timing of the ASP data into account in promulgating the Final Rule.

3. Reduce Bundle "Leakage"

When the bundle was established, certain factors were included to better ensure appropriate payment, particularly for sicker, higher-cost patients. However, providers do not receive the full base rate for each treatment. We refer to this lost reimbursement as "leakage." The following recommended changes would decrease leakage and allow all providers to receive the full base rate intended for treatment of patients on dialysis. While Sec 1881(b)(14)(D) calls for a "case mix adjustment" and an "outlier" adjustment, the Secretary has discretion as to what may be included in the case mix adjustment. Moreover, while CMS has proposed a 1% outlier threshold, the Secretary is not bound by any specific threshold for outliers and could set a lower threshold in the Final Rule. We recommend:

- Suspend the Comorbidity Adjustors. Not all dialysis providers are able to capture all the data necessary to document all comorbidities for patients. In addition, many of the requirements CMS applies are not applicable to a typical patient with a comorbidity adjustor. For example, for a provider to document that a patient has pneumonia, there must be a positive sputum culture even though many patients with pneumonia do not have a positive sputum culture.

  Small and nonprofit providers are disproportionately more likely to be impacted by the current application of the comorbidity adjustor because they do not have the infrastructure necessary to collect these data, particularly for acute comorbidities. We note that one of our members, Northwest Kidney Centers, has devoted a great deal of effort to the collection of data concerning patient comorbidities and still does not collect the amount anticipated in the University of Michigan Kidney Epidemiology and Cost Center (KECC) data for comorbidity adjustors. We recommend that CMS suspend use of comorbidity adjustors and work with stakeholders to identify a set of comorbidity factors that are both relevant and implementable.

- Set the Outlier Payment to *No More Than* 0.5%. According to the 2013 ESRD Proposed Rule, CMS only used about 52% of the outlier pool in 2011. As a result, over $1 per treatment was effectively removed from the base rate. The 2014 ESRD Proposed Rule notes that outlier payments represented only 0.2%—well short of the 1% target. We are concerned that smaller and nonprofit providers are disproportionately impacted by this provision because they do not have the infrastructure of larger providers and therefore are less likely to capture all of the costs for a patient. The net effect is that a provision that was originally put into place to protect small

providers is actually penalizing them by decreasing the base rate. We recommend that CMS either suspend or, if that is not feasible, lower the outlier withhold from 1.0% to 0.5%.

- Use Most Recent Data to Change the Standardization Factor. All dialysis providers are estimated to lose several dollars per treatment because the standardization factor does not utilize the most recent cost data for these services, but small and nonprofit providers are disproportionately penalized because their costs are often higher.

Administrative and Training Costs

A thorough analysis of costs should include those that have increased since the initiation of the bundle. The most significant of these is the expense for participation in CROWNWeb. In addition, all providers must pay the cost for administration of Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, and bear additional expenses from participating in the National Healthcare Safety Network (NHSN). The Proposed Rule includes additional costs for the transition to ICD-10, including the crosswalk necessary for comorbidity adjustors. We urge CMS to recognize this additional financial burden for compliance with these reporting requirements and make an appropriate adjustment to the bundle.

Self-Dialysis and Home Dialysis Training Add-On Adjustment

We appreciate CMS's attention to payment for self-dialysis and home dialysis training, including the number and length of training sessions and the associated costs. Several recent studies point to improved health status as well as better quality of life for patients receiving treatment in home. We believe that effective self and home dialysis requires adequate training and support, but the current add-on payment is inadequate to properly prepare a patient to assume the responsibility of self/home care. Indeed, the requirements that CMS imposes clearly exceed the payment for training a patient and the patient's care partner by a Registered Nurse. Accordingly, we recommend that CMS update the basis for the add-on payment and provide for an annual update, reflecting the rising cost of nursing salaries. While we understand CMS's concern about the potential for abuse or "gaming," we do not believe that a holdback is appropriate. Even under the best of circumstances, it is unlikely that CMS payment for training will contribute to such a development. As an alternative, CMS could monitor provider performance by tracking home dialysis take-up rates and continuance.

Phase-In

In the Proposed Rule, CMS asks for comment on a phase-in of the proposed reduction in the bundle amount. First and foremost, we urge CMS to significantly reduce the total reduction prior to contemplating any phase-in of the Final Rule. Simply phasing in the proposed reduction will fail to adequately protect beneficiary access and quality of care. Moreover, the proposed reduction would

likely lead to further consolidation in an already highly consolidated industry. Depending on the amount of the final reduction, we recommend a phase-in such that no single-year reduction would exceed $5 per treatment per year. The phased-in reduction should be accomplished in such a manner that it does not have any compounding effects over time, meaning that the net aggregate reduction should not be affected by the magnitude or duration of the phase-in. And, depending on the magnitude of the reduction in reimbursement, CMS should consider a smaller cut in the first year to enable providers to plan in a more careful and deliberate manner. This approach would also give CMS more time to address the problem of leakage, noted above. With a slowly phased-in reduction, providers will be better able to manage the reduction so as to protect beneficiary access and quality of care.

Conclusion

Thank you for the opportunity to comment on the proposed ESRD PPS. The NKCA is very concerned about the dramatic proposed reduction in reimbursement of $29 per treatment and believes that, if finalized, it will have a significant adverse effect on the provision of care, particularly in areas with a large proportion of low-income beneficiaries. In addition, we believe that the proposed cut would lead to further consolidation within the industry.

We believe that CMS can and should drastically reduce the magnitude of the proposed cuts and should phase in any reduction in payment at a rate of no more than $5 per treatment per year. Steps that CMS can take to mitigate the magnitude of the cut include (as discussed above): 1) methodological changes by the Moran Company, 2) more current and accurate cost data for ESAs, 3) suspending or reducing the comorbidity adjustor and outlier payment, and 4) properly considering the administrative and training costs necessary to comply with various reporting requirements.

We hope that CMS carefully considers these recommendations. We would be glad to discuss any of these suggestions in greater detail at any time. If you have any questions, please feel free to contact Martin Corry at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,

Martin Corry

Martin Corry
Executive Director