August 25, 2015

Andy Slavitt, MBA
Acting Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1614-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program (CMS–1628–P)

Dear Mr. Slavitt:

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) at the United States Department of Health and Human Services (HHS) related to its July 1, 2015 proposed rule, “Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program.” Representing more than 90,000 registered dietitian nutritionists (RDNs),1 dietetic technicians, registered (DTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States and is committed to improving the nation’s health through food and nutrition across the lifecycle. RDNs provide medical nutrition therapy in dialysis facilities, clinics, hospitals, university settings, and private practice. Through their direction and leadership, RDNs strive to advance the nephrology nutrition clinical practice, education, and research while promoting continuing education programs for dietitian nutritionists and other healthcare professionals.

The Academy generally supports CMS’s continued implementation and improvement of the case-mix adjusted bundled prospective payment system (PPS) for Medicare outpatient End-Stage Renal Disease (ESRD). The Academy continues to support quality improvement programs (QIPs) when conscientiously designed to effectively assess facility performance measures and assure and incentive quality ESRD services that foster improved patient outcomes. The Academy offers these comments to CMS regarding certain factors and reported performance measures, including:

- ESRD PPS base rate and the labor-related share;
- Fluid ultrafiltration rate;
- CMS’s drug designation process; and
- Quality measures for hypercalcemia.

1 The Academy recently approved the optional use of the credential “registered dietitian nutritionist (RDN)” by “registered dietitians (RDs)” to more accurately convey who they are and what they do as the nation’s food and nutrition experts. The RD and RDN credentials have identical meanings and legal trademark definitions.
**ESRD PPS Base Rate and High Cost Outliers**
The Academy supports CMS’s adjustment of payment amounts based upon the updated regression analysis and urges CMS to ensure stagnation in the payment rate does not negatively impact patient care. Specifically, the Academy is concerned about payments to rural ESRD facilities and appreciates CMS’s consideration of the potentially disproportionate impact on them. The Academy supports CMS’s proposed low-volume and rural payment adjustments that are necessary to ensure beneficiaries’ access to services where they may otherwise lack dialysis options.

The Academy continues to support CMS’s implementation of section 1881(b)(14)(D)(ii) of the Social Security Act allowing for a payment adjustment and the proposed recalibration of the fixed dollar loss amounts for high cost outliers due to unusual variations in the type or amount of medically necessary care.

**Update to the Labor-Related Share**
We support CMS’s continued labor-related share of 50.673 percent, that recognizes the enhanced role of RDNs and other providers in improving outcomes and promoting therapy adherence, including dialysis treatments, dietary recommendations, and medication regimes.

**Ultrafiltration Rate**
The ultrafiltration rate reporting measure has been studied for some time and the consensus is that rates higher than 13 ml/hour/kg increase the risk of cardiovascular mortality in our patients. Rapid ultrafiltration is associated nausea, vomiting, headache, fatigue, cramping, hypotensive episodes during dialysis, and feeling sick after dialysis. Patients remain fluid overloaded with subsequent poor blood pressure control leading to left ventricular hypertrophy, diastolic dysfunction, and high cardiovascular mortality.

The Academy encourages CMS to ensure that time of dialysis should be adjusted in such a way that patients would not suffer from symptoms related to rapid ultrafiltration. Monitoring Kt/V solely instead of taking into consideration the greater role of fluid management and removal is likely to result in more problems and sickness for patients, potentially impacting quality of life. While correction of uremia remains important, limiting our focus on the rate of fluid removal is to the detriment of our patients, leading to an increase in the risk of cardiovascular death. The Academy is mindful of the need to pursue a rate that further lowers the mortality rate in our patient population.

**Drug Designation Process**
The Academy recognizes the additional costs and benefits associated with furnishing new injectable and intravenous renal dialysis services not currently reflected in the ESRD PPS

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bundled payment, and agrees that the benefits of new injectables must be accounted as an increase in the bundle. Academy members’ experiences confirm recent research showing that oral-only calcimimetics increase patients’ pill burden, are dependent upon the physician’s willingness to prescribe them, are costly and are not demonstrably cost-effective in the long-term, and that their use is dictated by patients’ tolerance and willingness to regularly take the medications that may not be assuredly proven to enhance quality or length of life (even with a concomitant decrease in parathyroidectomy surgeries).

The Academy notes that we can expect approval of new injectables that will be used to treat or manage CMS’s bone and mineral metabolism category. Although calcimimetics are presently oral-only drugs, effective IV calcimimetics have successfully completed stage 3 clinical trials that should make them available in the very near future. In fact, Amgen just submitted a new drug application with the FDA on August 25, 2015 for its injectable calcimimetics, etelcalcetide. These promising new injectables are likely to disrupt the use of oral-only calcimimetics, and we appreciate CMS’s recognition it must “develop a computation for the inclusion of the oral and non-oral forms of calcimimetics so that the drug could be appropriately reflected in the ESRD PPS base rate.”

Quality Measures for Hypercalcemia
The Academy remains concerned about the proliferation of quality measures generally and appreciates CMS’s willingness to review measures used in the ESRD QIP for reasonableness. We recognize the statutory mandate in The Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93) requiring the Secretary to adopt measures in the in the ESRD QIP that are specific to the conditions treated with oral-only drugs for 2016 and subsequent years, but have concerns about whether the proposed hypercalcemia clinical

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3 Narayan R, Perkins RM, Berbano EP, et al. Parathyroidectomy versus cinacalcet hydrochloride-based medical therapy in the management of hyperparathyroidism in ESRD: a cost utility analysis. Am J Kidney Dis. 2007;49(6):801-13 (“In conclusion, in this analysis, we found that in patients with hyperparathyroidism refractory to conventional medical therapy who were candidates for either parathyroidectomy or cinacalcet therapy, the cost and cost utility of cinacalcet was most advantageous for patients who could expect a brief stay (16 months) on dialysis therapy. This would include those with a high risk of mortality or those who could expect to receive a transplant quickly. For other sub-groups, parathyroidectomy dominated.”).
measure can be appropriately characterized as a measure specific to conditions treated with oral-only drugs either (1) at present or (2) for the PY 2018 ESRD QIP.

Our first concern is that hypercalcemia is not presently a condition only treated with oral-only drugs. Hypercalcemia may be treated with calcimimetics, bisphosphonates (i.e., intravenous osteoporosis drugs that can lower calcium levels quickly and help rebuild weakened bone) or with IV fluids and diuretics often used during hospitalization to promptly lower extremely high calcium levels.

The Academy’s second concern is that hypercalcemia would only be treated with a calcimimetic when the calcium has risen due to treatment with active Vitamin D, which is typically given intravenously during hemodialysis. The Academy questions whether the regular use of IV Vitamin D in conjunction with calcimimetics (that are as of now “oral-only”) for a patient’s hypercalcemia negates the inclusion of that patient as having a condition treated with oral-only drugs.

The Academy recommends that CMS continue to track hypercalcemia, but believes that linking hypercalcemia to specific medications without including the influence of active Vitamin D is problematic and is unlikely to provide reliable data. In addition, the likelihood of FDA approval of new injectables to treat hypercalcemia before the PY 2017 collection period begins requires CMS to reconsider its proposed approach. Renal bone disease is a complex problem that is also significantly impacted by length and type of dialysis treatment, nutrition, and length of time with chronic kidney disease (prior to and when on dialysis).

**Conclusion**

The Academy sincerely appreciates the ongoing opportunity to offer comments regarding this important ongoing initiative, specifically related to proposed changes to the ESRD QIP. Please contact either Jeanne Blankenship by telephone at 202-775-8277 ext. 1730 or by email at jblankenship@eatright.org or Pepin Tuma by telephone at 202-775-8277 ext. 6001 or by email at ptuma@eatright.org with any questions or requests for additional information.

Sincerely,

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