

September 4, 2020

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Ms. Seema Verma, MPH  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1732-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

1120 Connecticut Avenue NW  
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Washington, D.C. 20036

***Re: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Dialysis Quality Incentive Program***

Dear Administrator Verma:

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services’ (CMS’s) on its proposed rule, *Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Dialysis Quality Incentive Program*, published in the July 13, 2020 issue of the Federal Register. Representing more than 107,000 registered dietitian nutritionists (RDNs),<sup>1</sup> nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of nutrition and dietetic professionals in the United States. 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 RDNs 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 also continues to support quality improvement programs (QIPs) when conscientiously designed to effectively assess facility performance measures and assure and incentivize quality ESRD services that foster improved patient outcomes without overburdening providers.

Overall, the Academy supports efforts aimed at achieving CMS's goals of better care, smarter spending, and healthier people. The Academy also supports the administration’s efforts to transform kidney care in America, including promoting home dialysis.<sup>2</sup> MNT provided by RDNs is a widely recognized component of medical guidelines for the prevention and treatment of many chronic diseases, including renal disease, as well as in the reduction of risk factors for these conditions. Medicare has reimbursed MNT for chronic kidney disease (CKD)

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<sup>1</sup> The Academy 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.

<sup>2</sup> <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/> and <https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html>. Accessed August 27, 2020.

since 2002 but is presently underutilized. As primary prevention, strong evidence supports optimal nutritional status as a cost-effective cornerstone in the maintenance of health, well-being, and functionality. As secondary and tertiary prevention, MNT is a cost-effective disease management strategy that reduces chronic disease risk, delays disease progression, enhances the efficacy of medical/surgical treatment, reduces medication use, and improves patient outcomes including quality of life.<sup>3</sup> Notably, research shows that patients with CKD receiving MNT were able to delay the time to dialysis and improve significant nutritional biomarkers, thereby saving Medicare money and improving patients' quality of life.<sup>456</sup>

The Academy offers these comments to CMS regarding certain factors contained in or related to the proposed rules, including:

- A. ESRD PPS Base Rate;
- B. Transitional Add-on Payment for New and Innovative Equipment and Supplies (TPNIES);
- C. Associate with National Kidney Foundation Comments;
- D. Utilize the 2020 Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline on Nutrition in Chronic Kidney Disease;
- E. Enable RDNs' Therapeutic Diet Ordering Ability in Dialysis Facilities; and
- F. Expand Access to Nutrition Care via Telehealth/Communication Technology Based Services

#### **A. ESRD PPS Base Rate**

The Academy supports CMS's proposal to change payment for calcimimetics from the transitional drug add-on payment (TDAPA) to the ESRD PPS base rate with eligibility for payment as ESRD outlier services starting for dates of service on or after January 1, 2021. We recommend that when outlier payments are less than 1 percent, that the remaining dollars are paid back to the dialysis facility to be invested in patient care.

The Academy supports CMS's proposed modifications to the low-volume payment adjustment (LVPA) to consider the impact of the COVID-19 public health emergency. The Academy questions the impact of the proposal to report any 6 months of data when the end of the PHE emergency is uncertain. Unfortunately, dialysis center volumes may be impacted for more than 6 months, thus negating the intent of the proposed modification. The Academy encourages CMS to consider an alternate proposal to address this potential scenario to ensure the intent of the proposal can be fully actualized.

In setting the ESRD PPS base rate, the Academy urges CMS to consider the impact of those rates on access to care in rural areas. In their March 2020 Report to Congress, MedPAC noted concern about the gap in the

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<sup>3</sup> Grade 1 data. Academy Evidence Analysis Library, <http://andevidencelibrary.com/mnt> [Grade Definitions: Strength of the Evidence for a Conclusion/Recommendation Grade I, "Good evidence is defined as: 'The evidence consists of results from studies of strong design for answering the questions addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias and flaws in research design. Studies with negative results have sufficiently large sample sizes to have adequate statistical power.'"]

<sup>4</sup> De waal D, Heaslip E, Callas P. Medical Nutrition Therapy for Chronic Kidney Disease Improves Biomarkers and Slows Time to Dialysis. *J Ren Nutr*. 2015.

<sup>5</sup> Bellizzi V, Calella P, Carrero JJ, Fouque D Very low-protein diet to postpone renal failure: Pathophysiology and clinical applications in chronic kidney disease. *Chronic Diseases and Translational Medicine*. 2018;4(1):45-50. <https://doi.org/10.1016/j.cdtm.2018.01.003>.

<sup>6</sup> Ikizler TA, Burrowes JD, Byham-Gray LD, et al; KDOQI Nutrition in CKD Guideline Work Group. KDOQI clinical practice guideline for nutrition in CKD: 2020 update. *Am J Kidney Dis*. 2020;76(3)(suppl 1):S1-S107.

Medicare margin between rural and urban facilities.<sup>7</sup> The proposal to cap any decrease in an ESRD facility's wage index is one way to address these access to care concerns, including access to RDNs. RDNs perform many roles in ESRD facilities aimed at improving outcomes and promoting therapy adherence, including dialysis treatments, dietary recommendations, and medication regimes. Rural facilities require an adequate margin to support recruitment and retention of qualified RDNs to address the needs of this nutritionally high-risk population. Our members who are responsible for hiring RDNs for rural area dialysis facilities report significant challenges in hiring and retaining RDNs for these sites, negatively impacting patient access to nutrition care. Another opportunity to better support access to care in rural areas is the opportunity to adopt a tiered approach to the LVPA using MedPAC's distinction for rural facilities adjacent to an urban area from rural non-urban adjacent facilities. Such an approach may ensure it applies the most dollars to facilities that are serving a critical patient need, but also likely operating at a loss.

#### **B. Transitional Add-on Payment for New and Innovative Equipment and Supplies (TPNIES)**

The Academy agrees with CMS's assessment of the application for a TPNIES for the Theranova 400 and Theranova 500 Dialyzers. A dialysis device that preserves albumin would unarguably have the potential to improve outcomes in dialysis patients. Unfortunately, the current evidence does not meet the criteria to qualify for the transitional add-on payment. The Academy shares CMS's hope that there will be sufficient evidence in the future to leverage such new and innovative equipment.

#### **C. Associate with National Kidney Foundation Comments**

The Academy associates itself with the comments submitted by the National Kidney Foundation on September 4, 2020.

#### **D. Utilize the 2020 Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline on Nutrition in Chronic Kidney Disease**

As noted in the proposed rule, low serum albumin is associated with increased mortality for dialysis patients. Unfortunately, serum albumin is often mistakenly used as a diagnostic criterion for malnutrition. While it is true that albumin is a prognostic indicator for outcomes such as hospitalizations and mortality, it is greatly influenced by fluid, chronic inflammation, and oxidative stress. Those things lessen its ability to be a good diagnostic criterion for malnutrition. As a result, the dialysis team looks to RDNs to develop and implement nutrition care plans aimed to resolve malnutrition when the low serum albumin may be reflective of these other factors. Evidence supports the Subjective Global Assessment (SGA) as a valid and reliable tool for assessing nutritional status in the ESRD population. The Academy of Nutrition and Dietetics and the National Kidney Foundation recently published the 2020 Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline on Nutrition in Chronic Kidney Disease.<sup>8</sup> The guideline includes three recommendations that speak to nutrition assessment:

##### **CKD: Single Biomarker Measurements**

In adults with CKD stages 1-5D or post-transplantation, biomarkers such as normalized protein catabolic rate (nPCR), serum albumin and/or serum prealbumin (if available) may be considered complementary tools to assess nutritional status. However, they should not be interpreted in isolation to assess nutritional status as they are influenced by non-nutritional factors (OPINION).

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<sup>7</sup> Medicare Payment Advisory Committee. March 2020. Report to the Congress: Medicare Payment Policy. Washington, DC: MedPAC.

<sup>8</sup> Ikizler TA, Burrowes JD, Byham-Gray LD, et al; KDOQI Nutrition in CKD Guideline Work Group. KDOQI clinical practice guideline for nutrition in CKD: 2020 update. Am J Kidney Dis. 2020;76(3)(suppl 1):S1-S107.

### **CKD: Serum Albumin Levels**

In adults with CKD 5D on MHD, serum albumin may be used as a predictor of hospitalization and mortality, with lower levels associated with higher risk (1A).

### **CKD: 7-Point Subjective Global Assessment (SGA)**

In adults with CKD 5D, we recommend the use of the 7-point Subjective Global Assessment as a valid and reliable tool for assessing nutritional status (1B).

It is important for dialysis centers to staff up to allow RDNs to follow evidence-based practice guidelines to achieve improved outcomes in this vulnerable population. The Academy encourages CMS to utilize the new guidelines as they set regulations and policies for CKD and ESRD services.

### **E. Enable RDNs' Therapeutic Diet Ordering Ability in Dialysis Facilities**

The ESRD Conditions for Coverage address a dietitian's personnel qualifications but do not address the RDN ordering therapeutic diets or other nutritional components. RDNs working in dialysis centers have the professional competency to independently order therapeutic diets for renal patients and should be permitted to do so in accordance with their state-legislated scope of practice. A renal dietitian nutritionist "[m]anages enteral/parenteral nutrition and specialized nutrition support therapy, including formula selection and adjustment based on patient/client laboratory results, using physician-approved protocols, clinical privileges for order writing, or similar documents consistent with facility organization policies."<sup>9</sup> We note that CMS has used rulemakings to specifically permit RDNs to order therapeutic diets in accordance with state law in hospitals, critical access hospitals, and long term care facilities, and further note that the practical implications for defining and ordering therapeutic diets are consistent across the continuum of care. Thus, the Academy encourages CMS to uniformly adopt its most recent interpretive coding guidelines for understanding therapeutic diets for dialysis facilities and across the continuum of care. In point of fact, therapeutic diets are both ordered in renal dialysis facilities, regulated by state and federal regulators, and essential to enhancing patient care.

RDNs' training and education best qualifies them to order patient diets both initially upon admission and after a nutrition assessment that considers the connection between a patient's complex medical problems, nutrition status, and actual nutrition risk. **The Academy strongly encourages CMS to ease patient and provider burdens by specifically allowing qualified RDNs, upon delegation of the authority by the attending physician, to independently:**

- Order all patient diets, including therapeutic diets;
- Order both standard house and disease-specific nutrition supplements;
- Order enteral nutrition or parenteral nutrition;
- Order nutrition-related laboratory tests needed to inform nutrition decisions and orders; and
- Order therapeutic diets in states that do not license RDNs if delegated ordering privileges by the attending physician and consistent with state law.

### **F. Expand Access to Nutrition Care via Telehealth/Communication Technology Based Services**

The current public health emergency has expanded the use of telehealth to deliver much needed medical and nutrition care services to Medicare beneficiaries. However, the current national emergency and mandates to practice social distancing have also exposed previous concerns and significant gaps in access to safe and

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<sup>9</sup> Kent PS, McCarthy MP, Burrowes JD, et al. Academy of Nutrition and Dietetics and National Kidney Foundation: revised 2014 standards of practice and standards of professional performance for registered dietitian nutritionists (competent, proficient, and expert) in nephrology nutrition. *J Acad Nutr Diet.* 2014;114(9):1448-1457.e45.

effective nutrition care for vulnerable Medicare beneficiaries. The temporary telehealth flexibilities enacted by CMS have helped to “modernize” aspects of telehealth services under the current Medicare program. But more needs to be done to address the needs of ESRD patients who, per the CDC, are more susceptible to COVID-19.

The Academy urges CMS to extend coverage and payment for monthly physician management visits for dialysis center patients delivered via telehealth to include the monthly management services provided by RDNs and permanently waive the geographic restrictions for telehealth services. Telehealth and telenutrition practice is firmly within RDNs’ professional scope of practice: “RDNs use electronic information and telecommunications technologies to support long-distance clinical health care [ ] RDNs use interactive electronic communication tools for[ ] the full range of MNT services that include disease prevention, assessment, nutrition focused physical exam, diagnosis, consultation, therapy, and/or nutrition intervention.”<sup>10</sup> Allowing RDNs to provide care to ESRD patients, including home dialysis patients, via telehealth aligns with the president’s directive in Executive Order 13890 to ensure “advances in telehealth services and similar technologies[ ] are appropriately reimbursed and widely available.”<sup>11</sup>

The emergence and rapid growth of telehealth and mobile technologies designed to improve the health of individuals, enhance patient engagement and lower costs should be recognized in all efforts to transform kidney care in America as it offers new opportunities to increase access to care in urban, suburban and rural areas and in all stages of kidney disease from early CKD to dialysis to post kidney transplantation. Time spent by all qualified health care professionals (both physician and non-physician providers) using such technologies for assessment, treatment, evaluation, and monitoring functions needs to be recognized in the ESRD PPS. Expanding current policies related to telehealth services beyond HPSAs and MSAs will assist Medicare beneficiaries living in urban and suburban areas who have limited mobility and transportation issues. Providing nutrition care to ESRD beneficiaries receiving home dialysis via telehealth has the potential to provide such care in a less distracting, quieter, and more private setting. Using motivational interviewing and supporting change takes rapport building, time to hear the patient and family express their thoughts, and an environment that offers the peace and ability to focus and not feel rushed.

The Academy appreciates the opportunity to offer comment on the ESRD PPS proposed rules. Please contact either Jeanne Blankenship at 312-899-1730 or by email at [jblankenship@eatright.org](mailto:jblankenship@eatright.org) or Marsha Schofield at 312-899-1762 or by email at [mschofield@eatright.org](mailto:mschofield@eatright.org) with any questions or requests for additional information.

Sincerely,



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<sup>10</sup> Academy of Nutrition and Dietetics Quality Management Committee. Academy of Nutrition and Dietetics: Revised 2017 Scope of Practice for the Registered Dietitian Nutritionist. *J Acad Nutr Diet.* 2018;118(1):141-165.

<sup>11</sup> Protecting and Improving Medicare for Our Nation's Seniors. 84 Fed. Reg. 53573 (October 8, 2019) (“Executive Order”).