July 16, 2024

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-5535-P
PO Box 8013
Baltimore, MD 21244-8013

Re: [CMS-5535-P] Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model

Dear Administrator:

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to provide comments on [CMS-5535-P] Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model published in the Federal Register on May 17, 2024.

The Academy represents over 113,000 registered dietitian nutritionists (RDNs), nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists; it is the largest association of nutrition and dietetics practitioners in the world and is committed to accelerating improvements in global health and addressing food and nutrition security and the effects it has on health and well-being.

RDNs’ extensive formal education and training provides expertise in all aspects of food and nutrition, enabling RDNs to play a key role in improving people’s nutritional status to prevent and treat chronic diseases and conditions. RDNs are recognized for their unique ability to conduct research and translate science and evidence through education, medical nutrition therapy (MNT) and intensive behavior therapy. The National Academies of Sciences, Engineering, and Medicine...
maintains that “the registered dietitian is currently the single identifiable group of health-care practitioners with standardized education, clinical training, continuing education and national credentialing requirements necessary to be directly reimbursed as a provider of nutrition therapy.”

Proposed definition of IOTA collaborators

The Academy supports the proposed definition of IOTA collaborators and appreciates CMS’s commitment to comprehensive patient care by including Registered Dietitian Nutritionists (RDNs) on the list of approved collaborators. Interdisciplinary care has shown to lead to better End-stage renal disease preparedness particularly in racial and ethnic minorities.1 RDNs deliver nutrition care services across various settings, including transplant hospitals and as outpatient Medicare Part B providers working with transplant patients. Their roles encompass evaluating transplant candidacy, offering pre- and post-surgery care, and providing long-term follow-up. RDNs deliver MNT to individuals with chronic kidney disease and those needing post-transplant care in clinics, physician offices, private practices, and via telehealth. Their expertise covers nutrition screening, assessment, diagnosis, intervention, and evaluation, addressing issues such as bone disease, malnutrition, fluid balance, and diabetes, while ensuring continuity of care and supporting medication management.2 Including RDNs as collaborators in the CMS program can help IOTA participants improve patient outcomes and enhance patient care.3,4

Recommendation:

1. Approve as proposed.

Proposed Quality Metrics

The Academy acknowledges CMS’s commendable focus on shared decision-making and care transition measures for the IOTA model to ensure consistent, high-quality care and optimize patient outcomes. However, a primary concern lies in the current model’s insufficient coverage of

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all facets influencing kidney transplantation and long-term success. Specifically, the model fails to fully address the multifaceted factors impacting transplant outcomes.

The post-operative period places significant metabolic stress on patients, necessitating adequate nutrition for recovery, immune function, and overall health. Literature and provider feedback confirm that nutritional challenges frequently arise among kidney transplant patients, yet monitoring and evaluating nutritional status are often overlooked. These nutritional challenges are not currently captured in proposed performance metrics.

Following organ transplantation, increased protein and calorie intake are crucial for wound healing, preventing compromised immune function, and mitigating malnutrition and associated complications, particularly among individuals with frailty pretransplant. The 2009 Kidney Disease: Improving Global Outcomes Clinical Practice Guideline for the Care of Kidney Transplant Recipients highlights noncompliance with diet and medication as a prevalent issue post-transplantation. While the patient reported outcome measure tools, CollaboRATE and CTM-3, suggested in the proposed model address medication adherence, they do not address patient understanding and adherence to nutrition care recommendations or prescribed therapeutic diets.

It is imperative for CMS to prioritize the gaps related to nutrition care in patient reported performance measures. These gaps include addressing patients’ understanding and adherence to supplementation, specialized dietary recommendations and/or prescribed therapeutic diets in the post-acute transplant period. There is also a demonstrated need for follow-up with RDNs and MNT services to reduce obesity and associated co-morbidities such as cardiovascular

The Care Transitions Measure-15 questionnaire could contribute to clearer understanding of post-transplant expectations by the patient as it includes features such as a written care plan and a list of upcoming appointments. These elements could aid in establishing appropriate care coordination for post-transplant MNT and help patients identify all areas of self-care including specialized dietary recommendations as written into the care plan. Addressing these gaps can enhance patient outcomes and provide a more comprehensive understanding of factors influencing organ transplant success.

**Recommendation:**

1. CMS should explore ways in which nutrition care can be addressed, to include developing metrics that support access and referral to RDNs for MNT and adherence to dietary and supplement recommendations. Integration of these metrics within the IOTA model’s performance measurement framework will better cater to the holistic needs of kidney transplant patients, thereby enhancing overall care quality.

**Health-Related Social Needs Screening and Data Reporting**

Screening for health-related social needs (HRSNs) is essential in healthcare, as it enables providers to identify and address the social and economic factors that significantly impact health outcomes. Identifying and alleviating barriers to health, such as food and nutrition insecurity, can positively influence the enrollee’s physical environment, medical condition, and social well-being.

Although our members have not reported encountering documented instances where an individual’s transplant status was directly affected by unmet Health-Related Social Needs (HRSNs), we recognize the significant impact that factors such as food insecurity can have on a patient’s nutritional status and overall health.

Adequate nutrition is crucial for maintaining overall health and optimizing post-transplant outcomes. Malnutrition or poor nutritional status,

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often a consequence of food insecurity\textsuperscript{22}, can lead to complications and adversely affect recovery and long-term health post-transplant.\textsuperscript{23}

Furthermore, current literature highlights significant disparities in the referral, evaluation, and inclusion of individuals on the organ transplant waiting list. These disparities are notably pronounced among racial and ethnic minorities, women, and patients from lower socioeconomic status groups.\textsuperscript{24} These populations face numerous barriers, including HRSNs, which can impede their progression through the transplant evaluation process.\textsuperscript{25}

Given these disparities, it is essential to implement comprehensive HRSNs screening and data reporting. By systematically identifying and addressing these social determinants of health, healthcare providers can better support vulnerable populations, ensuring they receive the necessary resources and care to improve their transplant eligibility and outcomes. Moreover, robust data reporting on HRSNs is crucial for informing policy changes and optimizing resource allocation. This approach can promote equity and enhance access to transplant services for all patients, ensuring that resources are directed to those who need them most.

Registered Dietitian Nutritionists (RDNs) and social workers are currently screening transplant recipients and referring them to community resources for support. However, our members report, and literature confirms, that there is often a lack of coordination between outpatient teams and transplant sites. Enhanced screening and data reporting, particularly regarding the outcomes of these screenings (such as acceptance to community support services or waitlisting), will be valuable in improving communication and meeting the resulting care needs. This approach aligns with value-based care principles by focusing on improving patient outcomes and ensuring efficient use of resources. CMS should also ensure that the process is straightforward and not overly burdensome to hospitals and providers.

**Recommendation**

1. Approve requiring health-related social needs screening and data reporting.
2. Include outcome of screening in reporting data.


Quality of Life Measures and Impacts

Literature indicates that the quality of life (QOL) often improves for patients who receive a kidney transplant.\textsuperscript{26}\textsuperscript{,}\textsuperscript{27}\textsuperscript{,}\textsuperscript{28}\textsuperscript{,}\textsuperscript{29}\textsuperscript{,}\textsuperscript{30} Anecdotal evidence suggests that patients anticipate a more liberal diet post-transplant. However, studies report that dietary intake post-transplant is often poor, increasing risks of morbidity and mortality due to malnutrition, which impacts QOL.\textsuperscript{31}

Malnutrition is associated with a higher risk of adverse outcomes such as infections, pressure ulcers, and reduced wound healing, necessitating additional hospitalizations and medical interventions.\textsuperscript{32} Studies have shown that approximately 1 in 5 kidney transplant recipients develop malnutrition, with the risk being even higher at 1 in 3 due to dietary shifts post-transplant.\textsuperscript{33}\textsuperscript{,}\textsuperscript{34} This can result in lower QOL scores in post-transplant patients. Other concerns include low physical activity, reduced physical functioning,\textsuperscript{35} and increased weight gain post-transplant\textsuperscript{36} all which can contribute to reduced QOL. Dietary interventions after renal...


transplantation can reduce body weight and improve lipid profiles, enhancing patient-reported QOL.\textsuperscript{37}

It’s crucial to include nutrition-related QOL aspects in surveys. Addressing nutrition-related QOL factors may improve patient outcomes by promoting adherence to medical regimens, reducing hospital readmissions, and improving overall health. Regular assessment helps track changes, allowing for earlier intervention and continuous care improvement. By prioritizing these aspects, healthcare providers can better meet the needs of post-transplant patients, leading to improved QOL and clinical outcomes.

The impact of nutrition on QOL for post-transplant renal beneficiaries can be measured by a variety of metrics and tools. For example, nutrition status can be assessed by the transplant hospital using the Global Composite Malnutrition Score and in the community setting using the Subjective Global Assessment (SGA). Overall QOL can be assessed with the Kidney Disease Quality of Life (KDQOL-36) instrument, which includes components about dietary restrictions and symptoms like nausea. Additionally, monitoring weight and laboratory data such as lipid profiles is recommended for early intervention and managing cardio-metabolic risks impacting long-term QOL.

**Recommendation**

1. Include measures for identifying malnutrition or “at-risk” of malnutrition.
2. Utilize the Kidney Disease Quality of Life (KDQOL-36) instrument to identify nutrition-related impacts to QOL.

**Other Barriers to Care**

Individuals are often not referred for transplants due to not meeting specific center parameters, such as body mass index (BMI). Literature review cites obesity as a primary reason for individuals not being referred and considered for organ transplants.\textsuperscript{38,39} Addressing obesity along with other nutrition-related conditions within community and dialysis settings, is an important first step in increasing those eligible for transplant status. Interventions such as MNT provided by an RDN can significantly enhance access to transplants as MNT supports improved weight management and BMI outcomes, which are essential for transplant eligibility.\textsuperscript{40}

Individuals who receive MNT for weight loss often experience significant health improvements, including reductions in BMI, greater weight reduction, and a higher likelihood of achieving 5% weight loss compared to those not receiving MNT.\textsuperscript{41, 42} Other benefits include improved quality of life and decreased waist circumference. While current literature focused on MNT for weight loss, CKD and transplant eligibility is limited, existing studies support its effectiveness in weight management for CKD and pretransplant populations.\textsuperscript{43, 44} Furthermore, a qualitative study analyzing pre-transplant patient experiences with weight loss and obesity found that patients often feel hopeless and alone in their weight loss journey; participants reported that they desired greater support from health care professionals in finding a balance between a kidney-friendly diet and a sustainable weight-loss plan. This underscores the important role of RDNs in providing the necessary guidance and support to help patients achieve their weight loss goals while maintaining kidney health.

Obesity is not the only barrier to transplant services. Some transplant candidates experience severe malnutrition and require tube feedings to increase weight and combat undernutrition. This condition places them at a heightened risk for perioperative complications, such as wound breakdown, infection, prolonged hospital stays, and early mortality.\textsuperscript{45, 46, 47}

Despite consensus\textsuperscript{48} that enteral feeding can effectively enhance weight gain, improve nutritional markers, and support better clinical outcomes for severely malnourished individuals, there have been troubling anecdotal reports of transplant candidates' waitlist status being adversely affected due to insurance denials for tube feed placements and the necessary enteral formulas. These denials not only delay necessary medical treatment but also risk exacerbating patients' malnutrition, thereby increasing their risk for complications and negatively impacting their eligibility and readiness for transplantation.\textsuperscript{49} Increased perioperative complications due to

\begin{itemize}
\item \textsuperscript{42} Bradley DW, Murphy G, Snetselaar LG, Myers EF, Qualls LG. The incremental value of medical nutrition therapy in weight management. Manag Care. 2013;22(1):40-45.
\item \textsuperscript{43} Factor KF. Weight loss counseling for dialysis patients to prepare for transplant. J Clini Nephrol. 2019; 3: 161-163. DOI: 10.29328/journal.jcn.1001042
\item \textsuperscript{45} Effects of body mass index at transplant on outcomes of kidney transplantation. Transplantation. 2007; 84: 981-987
\item \textsuperscript{46} Body Mass Index and outcome in renal transplant recipients: a systematic review and meta-analysis.BMC Med. 2015; 13: 1-18
\end{itemize}
malnutrition can lead to longer hospital stays, higher healthcare costs, and increased strain on healthcare resources.\textsuperscript{50}

Given these barriers, it is imperative for CMS to explore ways to support referrals for medical nutrition therapy and RDNs services to promote the identification and correction of nutrition-related conditions that impact transplant referrals for beneficiaries. Supporting the care provided by RDNs plays an important role in improving patient outcomes and ensuring greater access to life-saving transplants.

**Recommendation**

1. We request that CMS explore ways to support referrals for beneficiaries to medical nutrition therapy services before they require transplant services. This will help identify and correct nutrition-related conditions that impact transplant referrals. Additionally, we ask that CMS evaluate these barriers to care in future proposed regulations.

Thank you for your careful consideration of the Academy’s comments on the Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access Model. Please do not hesitate to contact Jeanne Blankenship by phone at 312-899-1730 or by email at jblankenship@eatright.org or Carly Léon at 312-899-1773 or by email at cleon@eatright.org with any questions or requests for additional information.

Sincerely,

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