



HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

Submitted via Regulations.gov

December 1, 2023

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

RE: Docket No: CMS-9891-NC; File Code 1210-ZA31; Request for Information;
Coverage of Over-the-Counter Preventive Services

Dear Division of Dockets Management,

The Healthcare Nutrition Council (HNC) is providing comments on the notice published October 4, 2023 in the *Federal Register* by the U.S. Department of Health and Human Services (HHS), Department of Labor (DOL), and Department of the Treasury (DOT) titled "Request for Information; Coverage of Over-the-Counter Preventive Services." HNC is an association representing manufacturers¹ of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), including those categorized as medical foods, and parenteral nutrition (PN). Our mission is to improve patient outcomes by advancing nutrition policies and actions that raise awareness and optimize access of essential nutrition support therapies across the continuum of care.

The Departments are seeking public input on how best to ensure coverage and access to over-the-counter (OTC) preventive services, including the benefits of requiring most health insurance plans to cover these services at no cost and without a prescription by a health care provider. The Departments seek to understand the potential challenges and benefits for consumers, plans, health care providers, and issuers to provide coverage at no cost for OTC preventive products without a required prescription.

HNC urges the agency to include foods for special dietary² use (FSDU) as a qualified medical expense, allowing patients to purchase these medically necessary products using their Health Savings Accounts (HSA), Flexible Savings Accounts (FSA), or Health Reimbursement Arrangements (HRA).³ FSDUs are specialized nutrition products which include those intended to provide supplemental or sole source nutrition for individuals who are at risk of malnutrition or

¹ HNC members are Abbott Nutrition, Nestle Health Science, and Nutricia North America.

² 21 CFR Part 105

³ Internal Revenue Service (IRS). Frequently asked questions about medical expenses related to nutrition, wellness, and general health. See Q14: Is the cost of nutritional supplements a medical expense that can be paid or reimbursed by an HSA, FSA, Archer MSA, or HRA? (added March 17, 2023). A14: Yes, but only if the supplements are recommended by a medical practitioner as treatment for a specific medical condition diagnosed by a physician. Otherwise, the cost of nutritional supplements is not a medical expense. Retrieved from <https://www.irs.gov/individuals/frequently-asked-questions-about-medical-expenses-related-to-nutrition-wellness-and-general-health>.



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cannot achieve adequate nutritional intake from a normal diet. For many individuals, various physical, social, emotional, and socioeconomic issues impact their ability to consume adequate food and nutrition, which places them at high risk for nutritional deficiencies and challenges, including malnutrition. Malnutrition is a public health issue that burdens health care providers, hospital readmission rates, institutionalization, and utilization of costly health care services.⁴ Malnutrition can complicate health conditions and lead to frailty, risk of falling, and pressure injuries.⁵ Furthermore, up to one in two older adults are at risk for malnutrition^{6,7} and FSDUs give patients a complete and balanced profile of macro- and micronutrients to help them meet their nutrition goals and move toward a healthy dietary pattern. The World Health Organization (WHO) recognizes malnutrition as a major problem affecting older adults and has published a strong recommendation that ONS, a type of FSDU, coupled with dietary advice should be recommended to older people affected by undernutrition.⁸ Younger populations also benefit from FSDUs, including ONS. These products are used following a young child's transition to solid foods and can play a role in complementing the diet of this population to support continued growth and development. Therefore, the Departments should be confident in the ability of FSDU to provide necessary nutrition that can be part of the preventive services resulting in healthy outcomes.

HNC stands ready to work with the Departments on our recommendations that could be considered as over-the-counter preventive services. Please contact Berit Dockter MPP, RD, LD at bdockter@healthcarenutrition.org or 202-207-1112 if you have any questions. Thank you for consideration of these comments. Please let me know if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Robert Rankin". The signature is written in a cursive, flowing style.

Robert Rankin
Executive Director

⁴ Alvarez-Hernandez J, Planas Vila M, Leon-Sanz M, et al. Prevalence and costs of malnutrition in hospitalized patients; the PREDyCES® Study. *Nutr Hosp.* 2012; 27(4): 1049-1059.

⁵ The Malnutrition Quality Collaborative. National Blueprint: Achieving Quality Malnutrition Care for Older Adults, 2020 Update. Washington, DC: Avalere Health and Defeat Malnutrition Today; 2020.

⁶ The Malnutrition Quality Collaborative. National Blueprint: Achieving Quality Malnutrition Care for Older Adults. Washington, DC: Avalere and Defeat Malnutrition Today. March 2017.

⁷ Kaiser, MJ; Bauer, JM; Ramsch, C; Ulter, W; Guigoz, Y; Cederholm, T; Thomas, DR; Anthony, PS; Charlton, KE; Maggio, M; Tsai, AC; Vellas, B; and Sieber, CC. Frequency of malnutrition in older adults: a multinational perspective using the mini nutritional assessment. *Journal of the American Geriatrics Society.* 2010; 58(9): 1734-1738.

⁸ World Health Organization. Integrated care for older people: guidelines on community-level interventions to manage declines in intrinsic capacity. Geneva: World Health Organization; 2017. License: CC BY-NC-SA 3.0 IGO. Retrieved from <https://www.who.int/ageing/publications/guidelines-icope/en/>.