

Improving outcomes through awareness and action

June 5, 2023

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services Attention: CMS–1785–P P.O. Box 8013 Baltimore, MD 21244-1850

Submitted electronically via www.regulations.gov

Re: [CMS-1785-P] Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership

Dear Administrator Brooks-LaSure:

The Healthcare Nutrition Council (HNC) appreciates the opportunity to provide feedback and comments on the Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) Proposed Rule for Fiscal Year (FY) 2024. 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.

Malnutrition care remains a critical gap area that is associated with multiple poor health outcomes, including hospital readmissions and declines in functional status, psychosocial well-being, and quality of life. HNC applauds CMS' efforts to close this critical gap in the FY 2023 Hospital IPPS and LTCH PPS Final Rule — CMS-1771-F via the inclusion of the Global Malnutrition Composite Score (GMCS) electronic clinical quality measure (eCQM) – (NQF #3592e) -- beginning with the Calendar Year (CY) 2024 reporting period/FY 2026 payment determination in the Hospital Inpatient Quality Reporting (IQR) Program and the Medicare Promoting Interoperability Program for eligible hospitals and Critical Access Hospitals (CAHs). However, there is more that needs to be done to address the issue of malnutrition in the healthcare system. We recognize this administration has prioritized health equity and supports improving patient quality care. HNC's recommendations as outlined below can help accomplish these goals.

<sup>&</sup>lt;sup>1</sup> HNC members are Abbott Nutrition, Nestle Healthcare Nutrition, and Nutricia North America.



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- I. HNC strongly supports inclusion of health equity measures for future years in the LTCH Quality Reporting Program (QRP), and in addition, strongly recommends the inclusion of nutrition quality measures.
- II. HNC strongly recommends that CMS adopt a diagnosis of malnutrition as a measure to address health equity in the LTCH QRP.
- III. HNC provides feedback and support for the following Hospital IQR Program's measure sets and eCQMs:
  - A. Adopting attestation-based structural measures Geriatric Hospital measure and the Geriatric Surgical measure, for the Hospital IQR Program.
  - B. Hospital IQR Program is proposing to adopt additional eCQMs for inclusion in the HAC Reduction Program: (1) Hospital Harm-Pressure Injury; and (2) Hospital Harm-Acute Kidney Injury.

#### **Importance of Addressing Malnutrition as a Key Gap Area**

As CMS develops population health strategies to improve health and to deliver consistent quality healthcare at an affordable cost, high-quality nutrition and malnutrition care for older adults should be at the top of the agenda. The number of adults aged 65 years and older is expected to reach 77 million by 2034,<sup>1</sup> and Medicare spending is projected to rise at a higher rate than overall health spending, therefore there is an urgency to secure the future of healthy aging, starting with nutrition.

Up to one in two older adults are at risk for malnutrition, <sup>2,3</sup> an important nutrition-related public health concern that impacts health outcomes, quality of life, and increases healthcare costs. Tragically the national deaths related to malnutrition have doubled from 9,300 deaths in 2018 to 20,500 deaths in 2022 according to the U.S. Centers for Disease Control and Prevention (CDC).4 Disease-associated malnutrition (DAM) is malnutrition that occurs from disease-related causes. DAM can manifest in patients across all spectrums of body mass index, ranging from under to overweight individuals. It is often multifactorial, including inflammatory responses. which can increase metabolic demand, decreased appetite, gastrointestinal problems, and difficulty chewing and swallowing, leading to decreased nutrient intake, which can diminish immune response and wound healing, and increase infection rates.5 The estimated cost for DAM in older adults is \$51.3 billion per year. 6 A Congressional Research Service (CRS) report documented "malnutrition affects 35% to 60% of older residents in long term care facilities and as many as 60% of hospitalized older adult patient in the U.S." Malnutrition affects approximately 20% to 50% of admitted hospital patients.8 However, this figure likely underestimates the total burden of DAM, given the diagnosis gap in hospitalized patients. In an analysis by the Agency for Healthcare Research and Quality (AHRQ), malnutrition was diagnosed in only about 8% of hospital stays.9

If unaddressed, malnutrition will only continue to increase the cost of care and likelihood of poor health outcomes, including increased complications, longer hospitalizations, and more readmissions. Malnourished patients and patients with nutrition-related or metabolic issues are frequently readmitted to the hospital. A study published in *HCUP Statistical Briefs*, developed by AHRQ, in 2016 found that malnutrition in U.S. hospitalized patients is associated with a more than 50% higher rate of readmission within 30 days, compared to patient stays not



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associated with malnutrition. Further, the average costs per readmission for patients with malnutrition were found to be 26-34% higher (\$16,900 to \$17,900) compared to those without malnutrition (\$13,400).<sup>11</sup> Hospitalized patients at risk of malnutrition are also more likely to be discharged to another facility or require ongoing healthcare services after being discharged from the hospital than patients who are not vulnerable to becoming malnourished.<sup>12</sup> A retrospective health economic study found that providing ONS to Medicare patients aged 65+ with any primary diagnosis was associated with a 16% reduction in length of stay and a 15.8% cost savings – an average of \$3,079 -- per episode.<sup>13</sup>

Based on the aforementioned evidence, it is essential that CMS make nutritional status a key component in both its reimbursement policies and its efforts to improve the quality and value of care delivery. This should include being mindful of the outsized clinical value of nutritional status, despite the fact malnutrition is often only indicated as a secondary or comorbid condition for many patients.

I. HNC strongly supports inclusion of health equity measures for future years in the LTCH QRP, and in addition, strongly recommends the inclusion of nutrition quality measures.

CMS is seeking input on the importance, relevance, and applicability of concepts under consideration for future years in the LTCH QRP. HNC is pleased that CMS is seeking this input, and strongly supports the inclusion of health equity measures.

The LTCH QRP currently has 18 measures for the FY 2024 program year, including Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). Malnutrition is a risk factor for severe clinical events, such as loss of lean body mass and risk of frailty and falls, and possibly worse outcomes after surgery or trauma since proper nutrition is critical for healing and recovery.

Malnutrition also contributes to sarcopenia. The prevalence of sarcopenia in intensive care unit (ICU) patients is documented at 56-71%. Regardless of hospitalization, it is estimated that 5-13% of adults over age 60 years and approximately 50% of adults over 80 years have sarcopenia. Adequate nutrition, and specifically adequate protein intake, can help attenuate the declines in muscle mass and function associated with sarcopenia, and reduce the risk of frailty and falls.

Malnutrition is a critical issue and travels with the patient through all healthcare settings. In one study, 42.5% of patients whose stay in an acute care hospital was equal to or greater than two weeks were diagnosed with malnutrition. Patients should be screened for malnutrition when admitted to an LTCH and rescreened throughout their stay and prior to transitioning to another setting to ensure continuity in care.

For these reasons, HNC strongly recommends that CMS include malnutrition as a quality measure in the LTCH QRP for future years.



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II. HNC strongly recommends that CMS adopt a diagnosis of malnutrition as a measure to address health equity in the LTCH QRP.

CMS recognizes significant and persistent inequities in healthcare outcomes exist in the United States. As CMS notes, belonging to an underserved community is often associated with worse health outcomes. CMS further acknowledges that social risk factors are the wide array of non-clinical drivers of health known to negatively impact patient outcomes, including socioeconomic status, housing availability, and nutrition, often inequitably affecting historically marginalized communities on the basis of race and ethnicity, rurality, sexual orientation and gender identity, religion, and disability. HNC is pleased that CMS is addressing these important and ongoing issues and is seeking comment on options for measures that address health equity.

Nutrition quality measures in LTCHs are essential to ensure at-risk patients are identified and cared for before experiencing worsening, associated outcomes. Early nutrition intervention can reduce readmissions and decrease malnutrition complication rates and costs of care. The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) requires development of quality measures. Screening, assessment, diagnosis, and intervention for malnutrition are notably missing from current CMS LTCH quality measures, even though malnutrition is common among residents and associated with increased risk for infections, readmissions, falls, impaired wound healing, pressure injuries, physical limitations, and even death.<sup>17</sup>

Nutritional status, and by consequence malnutrition, is often influenced by a variety of Social Determinants of Health (SDOH) domains. In many cases SDOH will have a drastic impact on the availability and quality of foods, how those foods can be prepared and consumed, and what foods will be commonly consumed as staple parts of the diet. As a result, SDOH shape a population's nutritional status and may result in certain populations, such as the elderly, disabled, and the poorest segments of society, becoming malnourished.

HNC strongly recommends that CMS adopt a diagnosis of malnutrition as a measure to address health equity, to ensure appropriate identification and nutritional management of malnourished patients, make reporting of health disparities based on social risk factors and race and ethnicity, rurality, sexual orientation and gender identity, religion, and disability more comprehensive, and to address gaps in health equity.

- III. HNC provides feedback and support for the following Hospital IQR Program's measure sets and eCQMs:
  - A. Adopting attestation-based structural measures Geriatric Hospital measure and the Geriatric Surgical measure, for the Hospital IQR Program.

**HNC** supports CMS' efforts to include geriatric measures in the Hospital IQR Program's measure set. HNC acknowledges the MAP Rural Health Advisory Group, MAP Hospital Workgroup and MAP Coordinating Committee's concern regarding the likelihood it would be burdensome on hospitals to report on both measures – particularly for rural hospitals – and supports the concept to potentially combine the measures to lessen the burden. **HNC** 



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recommends that CMS issue guidelines which state that nutrition care planning is included in the Attestation Domain 1: Identifying Goals of Care.

Age-related changes (appetite loss, limited ability to chew/swallow, polypharmacy, and cognitive/functional declines) commonly affect diet and nutrition. The most common form of malnutrition in older adults is protein-calorie malnutrition, which is associated with multiple poor health outcomes including decreased immunity, increased infection rates, delayed wound healing, and decreased respiratory and cardiac function, as well as increased healthcare costs.

Making the change to fully integrate malnutrition care (screening, assessment, diagnosis, care plans and interventions) into the Medicare system is a prudent investment because malnutrition care is a low-risk and low-cost solution that can help improve the quality of clinical care and decrease costs associated with negative outcomes. Timely screening and assessment followed by intervention can significantly improve health outcomes for adults, with studies finding:

- Decrease in avoidable readmissions by about 20%<sup>18</sup>
- 50% reduction in pressure ulcer incidence<sup>19,20</sup>
- Reduced overall complications<sup>21</sup>
- Reduced average length of stay of approximately two days<sup>18</sup>
- Decreased mortality<sup>22</sup>
- Improved quality of life<sup>23</sup>

A study where one Accountable Care Organization (ACO) in Chicago implemented a nutrition-focused quality improvement program and analyzed the cost savings and patient outcomes. In this study, the total cost-savings from reduced 30-day readmissions and hospital stays associated with nutrition intervention was over \$4.8 million; the net savings was over \$3800 per patient treated for malnutrition.<sup>24</sup> The quality improvement program in this study included malnutrition risk screening at admission, prompt initiation of oral nutritional supplementation for at-risk patients, and nutrition support and education for patients during the hospital stay and post discharge.

B. Hospital IQR Program is proposing to adopt additional eCQMs for inclusion in the HAC Reduction Program: (1) Hospital Harm-Pressure Injury and (2) Hospital Harm-Acute Kidney Injury.

The Hospital IQR Program is proposing to adopt three additional eCQMs, which CMS is seeking input on for inclusion in the HAC Reduction Program, including two that HNC is providing feedback on: (1) Hospital Harm-Pressure Injury eCQM (CBE #3498e) and (2) Hospital Harm-Acute Kidney Injury eCQM (CBE #3713e); both beginning with the CY 2025 reporting period/FY 2027 payment determination. These measures should be introduced in the HAC Reduction Program to address equity gaps in the rate and severity of patient harm events and healthcare-associated infections. HNC is providing the following feedback:

#### (1) Hospital Harm-Pressure Injury eCQM

Nutrition plays a vital role in promoting skin integrity and supporting tissue repair in the presence of chronic wounds such as pressure injuries (PIs). Individuals who are malnourished are at greater risk of polymorbid conditions, adverse clinical outcomes, longer hospital lengths of stay, PI development, and mortality, and incur increased healthcare costs compared with patients



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who are adequately nourished.<sup>25</sup> Strategies for PI prevention and management, including early identification and management of malnutrition and provision of specially-formulated oral nutritional interventions to at-risk patients, optimization of electronic health record systems to allow for enhanced administration, monitoring, and evaluation of nutritional therapies, and implementation of protocol-based computerized decision support systems, have been reported to improve outcomes.<sup>26</sup> HNC supports CMS' adoption of the Hospital Harm-Pressure Injury eCQM and recommends that it automatically trigger a mandatory submission of the Malnutrition eCQM. Implementing the automatic mandatory submission of the Malnutrition eCQM will strengthen the HAC Reduction Program to encourage patient safety best practices, which also prioritize the delivery of equitable care, in inpatient facilities.

#### (2) Hospital Harm-Acute Kidney Injury eCQM

Nutritional assessment is an imperative tool for the evaluation and clinical monitoring of patients with acute kidney injury (AKI). AKI is recognized as a systemic inflammatory syndrome, a pro-oxidative, proinflammatory, and hypermetabolic state exerting a profound impact on the course of the disease that is associated with AKI. Acute loss of renal function interferes with the metabolism of all micro- and macronutrients. Nutritional and metabolic management present a cornerstone in the care of these patients. Patients with AKI are at high-risk for developing malnutrition as a result of coexisting catabolic illness, therefore, protein-calorie wasting (PCW) is an important factor which influences the outcome of AKI.<sup>27</sup> Malnutrition in AKI patients is associated with increased incidence of complications, longer hospitalization, and higher hospital mortality.<sup>28</sup> HNC supports CMS' adoption of the Hospital Harm-Acute Kidney Injury eCQM and recommends that it automatically trigger a mandatory submission of the Malnutrition eCQM. Implementing the automatic mandatory submission of the Malnutrition eCQM will strengthen the HAC Reduction Program to encourage patient safety best practices, which also prioritize the delivery of equitable care, in inpatient facilities.

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In closing, addressing malnutrition and providing adequate nutrition care continues to be a crucial component in reducing hospital-acquired conditions, lowering healthcare costs, and improving the health and well-being of vulnerable Medicare beneficiaries. **HNC urges CMS to prioritize policies and initiatives that identify and treat malnutrition, encourage proper nutrition and the development of cost-effective nutrition therapy products, and that ensures access through adequate coverage and payment policies for nutrition therapy products**. HNC stands ready to work with CMS and all stakeholders to develop these policies as one means to improve the public health system. If you have any questions or would like additional information, please contact Sydni Arnone, Healthcare Nutrition Council, at sarnone@healthcarenutrition.org or (202) 204-8396.

Respectfully submitted,

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https://www.defeatmalnutrition.today/sites/default/files/documents/CRS\_Memo\_Malnutrition\_in\_Older\_Adults.pdf 
<sup>8</sup> Barker LA, Gout BS, Crowe TC. Hospital malnutrition: prevalence, identification and impact on patients and the healthcare system. Int J Environ Res Public Health. 2011;8(2):514-527.

<sup>18</sup> Sriram K, Sulo S, VanDerBosch G, et al. A Comprehensive Nutrition-Focused Quality Improvement Program Reduces 30-Day Readmissions and Length of Stay in Hospitalized Patients. JPEN. 2017;41(3):384-391.

<sup>20</sup> Meehan A, Loose C, Bell J, Partridge J, Nelson J, Goates S. Health System Quality Improvement: Impact of Prompt Nutrition Care on Patient Outcomes and Health Care Costs. J Nurs Care Qual. 2016;31(3):217-223.

<sup>21</sup> Tappenden KA, Quatrara B, Parkhurst ML, Malone AM, Fanjiang G, Ziegler TR. Critical Role of Nutrition in Improving Quality of Care: An Interdisciplinary Call to Action to Address Adult Hospital Malnutrition. J Acad Nutr Diet. 2013;113(9):1219-1237.

<sup>22</sup> Gomes F, Baumgartner A, Bounoure L, et al. Association of Nutritional Support With Clinical Outcomes Among Medical Inpatients Who Are Malnourished or at Nutritional Risk: An Updated Systematic Review and Meta-analysis. JAMA Network Open. 2019;2(11):e1915138-e1915138.

<sup>23</sup> Ha L, Hauge T, Spenning AB, Iversen PO. Individual, nutritional support prevents undernutrition, increases muscle strength and improves QoL among elderly at nutritional risk hospitalized for acute stroke: a randomized, controlled trial. Clin Nutr. 2010;29(5):567-573.

<sup>24</sup> Suela Sulo, PhD; Josh Feldstein, BA; Jamie Partridge, PhD, MBA; Bjoern Schwander, MS, RN; Krishnan Sriram, MD; Wm. Thomas Summerfelt, PhD. Budget Impact of a Comprehensive Nutrition-Focused Quality Improvement Program for Malnourished Hospitalized Patients. July 2017 Vol 10, No 5. Retrieved from: https://www.ahdbonline.com/issues/2017/july-2017-vol-10-no-5/2424-budget-impact-of-a-comprehensive-nutrition-focused-quality-improvement-program-for-malnourished-hospitalized-patients

<sup>25</sup> Munoz N, Litchford M, Cox J, Nelson JL, Nie AM, Delmore B. Malnutrition and Pressure Injury Risk in Vulnerable Populations: Application of the 2019 International Clinical Practice Guideline. Adv Skin Wound Care. 2022 Mar 1;35(3):156-165. doi: 10.1097/01.ASW.0000816332.60024.05. PMID: 35188483.

<sup>&</sup>lt;sup>1</sup> U.S. Census Bureau. Older People Projected to Outnumber Children for First Time in U.S. History. Updated October 8, 2018. Retrieved from: https://www.census.gov/newsroom/press-releases/2018/cb18-41-population-projections.html

<sup>&</sup>lt;sup>2</sup> The Malnutrition Quality Collaborative. National Blueprint: Achieving Quality Malnutrition Care for Older Adults. Washington, DC: Avalere and Defeat Malnutrition Today. March 2017.

<sup>&</sup>lt;sup>3</sup> 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.

<sup>&</sup>lt;sup>4</sup> Kaiser Health News. U.S. Malnutrition Deaths Have More Than Doubled. *U.S. News and World Report.* April 13, 2023. Retrieved from: https://www.usnews.com/news/health-news/articles/2023-04-13/deaths-from-malnutrition-have-more-than-doubled-in-the-u-s#:~:text=By%20Phillip%20Reese%20%7C%20KFF%20Health%20News&text=The%20same%20trend%20occurred%20nationwide,for%20Disease%20Control%20and%20Prevention.

<sup>&</sup>lt;sup>5</sup> Goates S, Du K, Braunschweig CA, Arensberg MB. Economic Burden of Disease-Associated Malnutrition at the State Level. PLoS One. 2016;11(9):e0161833-e0161833.

<sup>&</sup>lt;sup>6</sup> Snider JT, Linthicum MT, Wu Y, et al. Economic burden of community-based disease-associated malnutrition in the United States. JPEN. 2014;38(2 Suppl):77s-85s.

<sup>&</sup>lt;sup>7</sup> Dabrowska A. Malnutrition in Older Adults. March 8, 2017. Retrieved from:

<sup>&</sup>lt;sup>9</sup> Barrett ML, Bailey MK, Owens PL. Non-maternal and Non-neonatal Inpatient Stays in the United States Involving Malnutrition, 2016. U.S. Agency for Healthcare Research and Quality. Retrieved from: www.hcupus.ahrq.gov/reports.jsp.

<sup>&</sup>lt;sup>10</sup> Braunschweig C, Gomez S, Sheean PM. Impact of declines in nutritional status on outcomes in adult patients hospitalized for more than 7 days. J Am Diet Assoc. 2000;100:1316-1322.

<sup>&</sup>lt;sup>11</sup> Fingar K, Weiss A, Barrett M, Elixhauser A, Steiner C, Guenter P, and Hise Brown M. All-Cause Readmissions Following Hospital Stays for Patients with Malnutrition, 2013. HCUP Statistical Brief #218. 2018. 1-18.

<sup>&</sup>lt;sup>12</sup> Zapatero A, Barba R, Gonzalez N, et al. Influence of obesity and malnutrition on acute heart failure. Rev Esp Cardiol. 2012; 65(5): 421-426.

<sup>&</sup>lt;sup>13</sup> Thomas DR, Zdrowski CD, Wilson MM, et al. Malnutrition in subacute care. Am J Clin Nutr. 2002;75:308-313.

<sup>&</sup>lt;sup>14</sup>Goates, Scott; Kristy Du, Carol Braunschweig, and Mary Beth Arensberg. Economic Burden of Disease-Associated malnutrition at the State Level. *PLOS ONE*. 2016; 11(9): 1-15.

<sup>&</sup>lt;sup>15</sup> Traylor, Daniel; Stefan Gorissen, and Stuart Phillips. Perspective: Protein Requirements and Optimal Intakes in Aging: Are We Ready to Recommend More Than the Recommended Daily Allowance? *Adv Nutr.* 2018; 9:171-182

<sup>&</sup>lt;sup>16</sup> Bauer JD, Hiscocks K, Fichera R, Horsley P, Martineau J, Denmeade S, Bannister M, de Groot E, Lee S, Waterhouse M. Nutritional status of long-term patients in the acute care setting. Intern Med J. 2012 Nov;42(11):1251-4. doi: 10.1111/j.1445-5994.2012.02950.x. PMID: 23157519.

<sup>&</sup>lt;sup>17</sup> The Malnutrition Quality Collaborative. National Blueprint: Achieving Quality Malnutrition Care for Older Adults, 2020 Update. Avalere Health and Defeat Malnutrition Today; Washington, DC, USA: 2020. Retrieved from: https://www.defeatmalnutrition.today/sites/default/files/National\_Blueprint\_MAY2020\_Update\_OnlinePDF\_FINAL.pdf

<sup>&</sup>lt;sup>19</sup> Barrett ML, Bailey MK, Owens PL. Non-maternal and Non-neonatal Inpatient Stays in the United States Involving Malnutrition, 2016. U.S. Agency for Healthcare Research and Quality. Retrieved from: www.hcupus.ahrq.gov/reports.jsp



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<sup>&</sup>lt;sup>26</sup> Citty SW, Cowan LJ, Wingfield Z, Stechmiller J. Optimizing Nutrition Care for Pressure Injuries in Hospitalized Patients. Adv Wound Care (New Rochelle). 2019 Jul 1;8(7):309-322. doi: 10.1089/wound.2018.0925. Epub 2019 Jul 2. PMID: 31832278; PMCID: PMC6906754.

<sup>&</sup>lt;sup>27</sup> Anita Saxena, Dietary management in acute kidney injury, Clinical Queries: Nephrology,

Volume 1, Issue 1, 2012, Pages 58-69, ISSN 2211-9477, https://doi.org/10.1016/S2211-9477(11)70010-3.

<sup>&</sup>lt;sup>28</sup> Berbel MN, Pinto MP, Ponce D, Balbi AL. Nutritional aspects in acute kidney injury. Rev Assoc Med Bras (1992). 2011 Sep-Oct;57(5):600-6. English, Portuguese. doi: 10.1590/s0104-42302011000500022. PMID: 22012298.