January 28, 2016

Senate Finance Committee
U.S. Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators,

Abbott commends the Bipartisan Chronic Care Working Group on its multi-pronged efforts during the past months to explore , and draft policy options to improve the delivery of care to Medicare beneficiaries with chronic diseases. The promotion of e quality homecare andthe advancement of team-based care are important policy options to consider Also critical are the adoption of new innovations and technologies including telehealth, and the empowerment of individuals and caregivers in making health care decisions. . This letter is in response to the Working Group's request for comments specific to the content and questions outlined in the recently released draft Policy Options Document.

Abbott is a global healthcare company committed to helping people live their best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 74,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve. Abbott welcomes the opportunity to provide its ideas for chronic care reform in the Medicare program.

Nutrition status is a vital sign, especially for older adult health and helps form the baseline for clinical care, which is especially critical for those with chronic disease.[1] Chronic diseases can cause malnutrition because of dietary restrictions, impaired ingestion/absorption, and increased nutrient needs. In fact, poor nutrition has been specifically recognized as a chronic disease risk factor and identified as a care area where integration of best practices can help promote a systematic approach to the assessment and management of this complex population, including the prevention of additional co-morbidities.[2]

Malnutrition is a major concern because it can worsen health outcomes including higher chances of complications, readmissions and even death. Research documents show that malnourished older adults make more visits to physicians, hospitals and emergency rooms. Malnourished patients can continue to worsen even during an inpatient stay, which may lead to increased costs. Generally, care transition programs are limited in their inclusion of nutrition-specific recommendations and practices. Studies show that malnutrition, as a contributing factor to post-hospital syndrome, can increase a patient's risk for a 30-day readmission, often for reasons other than the original diagnosis.[3]

Malnutrition may be commonly viewed as resulting from hunger, food insecurity, or obesity. However, malnutrition can occur independent of socioeconomic or weight status. Many older adults may not even realize they are malnourished – they can be underweight, of normal weight, or overweight, but have low levels of muscle or lean body mass. The loss of muscle, strength and energy can intensify in malnourished patients and those with health issues like a heart attack or pneumonia. Further, well-nourished individuals can become malnourished when they experience physical trauma or stress such as disease, surgery, infection or injury, which can significantly speed up loss of lean body mass. Older adults are particularly at risk because their protein intake is often lower, thus increasing the risk of losing muscle and lean body mass more quickly and to a greater extent than younger

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[1] Watson et al. Nutrition as a vital sign: progress since the 1990 multidisciplinary Nutrition Screening Initiative and opportunities for nursing. J Nurs Care. 2014; 4:224.
[2] HHS Multiple Chronic Conditions: A Strategic Framework; Dec 2010, p. 11 and 16
[3] Krumholz HM. Post Hospital Syndrome-an acquired, transient condition of generalized risk. N Engl J Med. 2013;368:100-102.

adults. The result is increased length of recovery from hospitalization or illness as well as decreased strength, mobility, and independence which can result in increased health care costs if an individual can no longer stay at home or requires skilled nursing, rehabilitation or long-term care services.

We commend the Senate Finance Committee Working Group for exploring innovative policy options to break down barriers across the care continuum and allow Medicare Advantage Plans to expand supplemental benefits to help ensure quality care and improved health outcomes. Screening and appropriate management of disease-related malnutrition for beneficiaries with chronic conditions have been demonstrated to improve outcomes and decrease costs across healthcare settings. However, incentives currently are not aligned for early identification, nutrition intervention and care coordination of malnourished and at-risk beneficiaries. Thus malnutrition remains a hidden, yet persistent problem for older adults with chronic disease.

Including malnutrition care (detailed below in three of the proposed policies for chronic disease management)presents an opportunity for addressing a gap and improving quality care and health outcomes for Medicare beneficiaries.

1. **Adapting Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees**

We support giving Medicare Advantage plans the flexibility to establish a benefit structure that varies based on the chronic conditions of individual enrollees. Malnutrition is important to address in providing these tailored benefits, because it is prevalent in older adults with chronic disease. For example, studies have estimated the prevalence of malnutrition in cancer patients to be 30% to 87%[4] (depending on the type of cancer), and malnutrition affects between 20% and 50% of patients at different stages of Chronic Kidney Disease,[5] and between 19% and to 60% of COPD patients depending on the population studied and the assessment used.[6] In addition, demographic factors among older Americans may contribute to healthcare disparities related to malnutrition.

Nutrition status can also impact the health outcomes and potential progression of the chronic conditions affecting Medicare Advantage enrollees. Medicare beneficiaries with multiple chronic conditions are more likely to be hospitalized and those with two or more chronic conditions account for almost 98% of hospital readmissions.[7] Importantly, malnutrition is highly relevant for this vulnerable population as it is an independent predictor of negative patient outcomes, including mortality, increased length of hospital stay, readmissions, and greater hospitalization cost.

Malnutrition is a patient safety risk as well. Tthose who are malnourished are more likely to experience a healthcare acquired condition. Malnutrition is linked to numerous complications including: increased rates of hospital morbidity, increased incidence of hospital-acquired pressure ulcers[8] and infections, falls, delayed wound healing,[9] decreased respiratory and cardiac function, poorer outcomes for chronic lung diseases, increased risk of cardiovascular and gastrointestinal disorders, reduced physical function anddevelopment of nosocomial infections,[10] and impairment of non-specific and cell-mediated immunity.[11] Malnutrition has also been identified as

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[4] Kumar NB. Nutritional Management of Cancer Treatment Effects.2012.

[5] Pupim, L.B. et al. Nutrition and metabolism in kidney disease. Seminars in Nephrology. 2006;26:134-157.

[6] Hunter AM, et al. The nutritional status of patients with chronic obstructive pulmonary disease. Am Rev Respir Dis. 1981;124(4):376–381.

[7] Centers for Medicare and Medicaid Services. Chronic Conditions Among Medicare Beneficiaries Chartbook: 2012 Edition Website. Available at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf. Accessed on June 21, 2015.

[8] Jensen GL, et al. Adult starvation and disease-related malnutrition: A proposal for etiology-based diagnosis in the clinical practice setting from the International Consensus Guideline Committee. J Parenter Enteral Nutr. 2010; 34:156-159.

[9] Barker LA, et al. Hospital malnutrition: prevalence, identification and impact on patients and the healthcare system. Int J Environ Res Public Health. 2011;8:514-527.

[10] Braunschweig C, et al. 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.

[11] Beattie AH, et al. A randomised controlled trial evaluating the use of enteral nutritional supplements postoperatively in malnourished surgical patients. Gut 2000;46:813-818.

the strongest independent risk factor predicting short-term mortality in elderly patients visiting the emergency department.[12]

Recommendation: *We recommend including registered dietitian nutritionists/other clinically qualified nutrition professionals and community-based nutrition programs in the network of Medicare Advantage providers who address chronic conditions and work to prevent the progression of chronic disease through care improvement plans. We also recommend that malnutrition therapies, such as oral nutrition supplements, be allowed in Medicare Advantage programs as an additional supplemental benefit related to the treatment of the chronic condition and/or the prevention of the progression of the chronic disease.*

2. **Expanding Supplemental Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees**

We support allowing Medicare Advantage plans to offer a broader array of supplemental benefits than they do today. We agree with the Working Group's assessment that "A wide range of non-medical or social factors, such as **nutrition**, are important contributors to the health and costs of chronically-ill individuals."

Disease-related malnutrition affects about 10% of chronically ill patients in the community and between 30% and 50% of patients admitted to hospitals and 21% to 51% in long-term care. The morbidity, mortality, and direct medical costs associated with disease-related malnutrition impose a substantial social burden, with the cost to the U.S. estimated to be $51.3 billion for individuals aged 65 years and older.[13] As the elderly are expected to live longer, population susceptibility to chronic disease is increased and the impact of disease-related malnutrition on society is also likely to increase.

Malnutrition care is a low-risk, low-cost clinical strategy. It includes a range of evidence-based services and therapies, from increased access to registered dietitian nutritionists/other clinically qualified nutrition professionals and community nutrition programs for education and counseling, to the use of enteral nutrition or oral nutrition supplements.

For example, care transition programs should consistently communicate nutritional status and nutrition care plans for the receiving facility and healthcare practitioners. Communication of a patient's nutritional status and recommended care plan with primary care physicians and other providers post-discharge is critical to ensure patient safety and continuity of care and to promote healing and recovery. Use of specific tools and protocols for nutrition intervention (such as checklists and a catalog of community resources) can help ensure that all patients and family caregivers get the necessary support and services to address malnutrition.

Evidence demonstrates that nutrition intervention can lower costs by decreasing preventable readmissions, complications, length of hospital stay (LOS), and mortality. For example, Fresenius Medical Care conducted a non-randomized study in the End Stage Renal Disease population and found oral nutrition supplements associated with significantly longer survival.[14] Another retrospective Health Economics Outcomes Research study supported by Abbott demonstrated that nutrition intervention with oral nutritional supplements provided to hospitalized Medicare patients ≥65 was associated with a significant decrease in probability of 30-day hospital readmission (↓8.4%), reduced LOS (↓16%), and decreased episode costs (↓15.8% or $3,079).[15] Significantly, hospitalized Medicare patients ≥65 with a diagnosis of Acute Myocardial Infarction (AMI), Chronic Heart Failure (CHF), and Chronic Obstructive Pulmonary Disease (COPD) who were provided oral nutrition supplements were also

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[12] Gentile S, et al. Malnutrition: a highly predictive risk factor of short term mortality in elderly presenting to the emergency department. J Nurt Health Aging. 2013; 17(4):290-294.

[13] Snider J et al: Economic burden of community-based disease-associated malnutrition in the United States. JPEN J Parenter Enteral Nutr 2014;38(2 Suppl):77S-85S.

[14] Lacson et al, "Outcomes associated with intradialytic oral nutritional supplements in patients undergoing maintenance hemodialysis: a quality improvement report. Am J Kidney Dis. 2012;60:591–600.

[15] Lakdawalla et al. Can oral nutrition supplements improve Medicare patient outcomes in the hospital? Forum for Health Economics and Policy. 2014

associated with a decrease in LOS, episode costs, and a reduced probability for hospital readmission within 30 days with ↓12.0%, ↓10.1% and ↓13.1%[16] respectively.

Additionally, a recent prospective, randomized placebo controlled clinical trial supported by Abbott demonstrated that use of a new class of oral nutrition supplements by malnourished patients with a heart or lung disease was associated with a 50% lower death rate 90 days following hospitalization compared to placebo. While the study results showed no significant differences between the intervention and control groups on the combined endpoints of hospital readmissions or death, analysis of the individual components showed significant improvements in other health outcomes including nutritional status and Vitamin D levels at 30 and 60 days.[17] This study builds upon existing research that shows the role nutrition plays in a patient's health, ranging from rebuilding muscle mass to helping with recovery from disease and reducing time in the hospital. The nutrients in the specialized nutrition supplement used in the study – high protein (20 grams), B-hydroxy-B-methylbutyrate or HMB (a muscle preserving ingredient) and Vitamin D – are all important components in repairing and rebuilding muscle while recovering from hospitalization and illness.

Recommendation: *We recommend that a standard nutrition benefit be allowed as part of the additional supplemental benefits Medicare Advantage plans offer to improve the overall health of individuals with chronic disease. A standard nutrition benefit would include systematic malnutrition screening of beneficiaries with chronic conditions, assessment as warranted by a positive screening,development of a nutrition care plan as needed (from hospitalization through discharge), and access to clinical nutrition interventions; i.e., education, counseling, enteral or parenteral nutrition, oral nutrition supplements, vitamins and/or mineral supplements.*

3. Developing Quality Measures for Chronic Conditions

We support the Report recommendation that the Centers for Medicare & Medicaid Services include in their quality measures plan the development of measures that focus on the health care outcomes for individuals with chronic disease.

Given the prevalence of malnutrition as a co-morbid condition among individuals with chronic diseases and the negative outcomes related to malnutrition, it is critical to identify patients who are at-risk and to implement a care plan based upon assessment and diagnosis. Early intervention and continuity of care prior to discharge with patient education, diet orders, and community-based nutrition services is critical to across the care continuum to improving quality and decreasing costs.[18]

Despite a significant negative impact on patient outcomes and costs malnutrition care is an area that has largely remained unaddressed under Medicare quality programs and presents an opportunity for improved performance. There are currently no quality measures to address gaps in management of malnutrition for adults with chronic diseases. Gap areas include lack of systematic (1) screening, assessment, and nutrition intervention; (2) execution of nutrition care plans upon admission through discharge; and/or (3) care coordination to home or other post-acute care sites. Further, standardized nutrition documentation in the EHR is critical for patient safety and coordination of care.

To further advance quality measurement in malnutrition care, Avalere Health, the Academy of Nutrition and Dietetics and other stakeholders have recently joined together to launch a national "Malnutrition Quality Improvement Initiative Demonstration". The focus of this collaboration is to improve quality malnutrition care

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[16] Snider et al. The impact of oral nutrition supplementation in Medicare patients with COPD. Value in Health. May 2014.

[17] Deutz et al. Readmission and mortality in malnourished, older, hospitalized adults treated with a specialized oral nutritional supplement: A randomized clinical trial. Clin Nutr. 2016; in press.

[18] Tappenden et al. Critical role of nutrition in improving quality of care: an interdisciplinary call to action to address adult hospital malnutrition. JPEN J Paren Enter Nutr. 2013, 37: 482-497.

with an interdisciplinary care team toolkit to enhance care coordination and advance tools that can be integrated into EHR systems.[19]

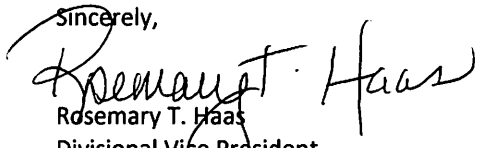
Action in this area aligns with CMS' National Quality Strategy and many of the Committee's goals for quality improvement, care coordination, patient empowerment and engagement, and improved care for Medicare Advantage patients. Nutritional status is critical in helping older adults with chronic conditions to maintain mobility and independence. As such, there is an opportunity to address this measure gap and to align incentives for providers by standardizing a malnutrition-related measure(s) across acute and post-acute care quality programs for beneficiaries with chronic conditions.

Recommendation: *We recommend the following quality-focused actions:*

- *Include malnutrition-related quality measures in three of the measure development plan areas under consideration by the Working Group specifically in the patient and family engagement, care coordination, and community-level quality measures.*
- *Implement a malnutrition-related quality measure set in Medicare and private accountability programs including Value-Based Purchasing, Medicare Shared Savings, Medicare Advantage and State quality programs for acute and post-acute care as soon as feasible.*
- *Include a "nutritional status domain" in the Medicare Post-Acute Care Quality Programs to align incentives with nutritional status as a key indicator of adult health.*

CONCLUSION: Medicare beneficiaries with chronic conditions are at increased risk of malnutrition. Malnutrition screening, assessment, and intervention should be a routine standard of medical care and should be effectively managed across the care continuum. However, this remains a gap area. We believe including malnutrition care in the Working Group's proposed policy options will help improve outcomes and decrease medical costs as well as make a meaningful difference in the lives of Medicare beneficiaries living with chronic disease.

Sincerely,



Rosemary T. Haas
Divisional Vice President
Federal Government Affairs, Abbott

[19] *Launching the Malnutrition Quality Improvement Initiative.* Avalere, November 2015. Available at http://avalerehealthproduction.s3.amazonaws.com/uploads/pdfs/1418926720_Avalere_Health_MalnutritionLaunching_WhitePaper.pdf