BEFORE THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

In re: Medicare and Medicaid Programs; Part II—Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction	))))))))	**File Code CMS-3267-P**

<u>COMMENTS OF THE CERTIFICATION BOARD FOR NUTRITION SPECIALISTS</u>

The Certification Board for Nutrition Specialists (CBNS), by counsel, hereby submits comments in response to the above referenced Proposed Rule, 78 Fed. Reg. 9216 (Feb. 7, 2013). CBNS addresses the proposed revisions to the hospital requirements in 42 CFR Part 482, Section 482.28 (concerning Food and Dietetic Services). In particular, CBNS alerts CMS to an apparently unintended consequence of the rule revision that could deny patients reliable access to competent and effective therapeutic diet ordering. CBNS also herein provides a recommendation for modification of the Proposed Rule that will ameliorate that unintended consequence.

<u>Summary of Proposed Rule</u>

CMS states the purpose of the proposed rule is to comport with Executive Order 13563, "Improving Regulations and Regulatory Review", in which the President recognized the importance of a streamlined, effective, and efficient regulatory framework designed to promote economic growth, innovation, job-creation, and competitiveness.

CMS proposes to amend existing 42 CFR Part 482, Section 482.28(b)(1),(2) to read as follows:

(b) * * *

(1) Individual patient nutritional needs must be met in accordance with recognized dietary practices.

(2) All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified

> dietitian as authorized by the medical staff and in accordance with State law.

See 78 Fed. Reg. 9242.

In the Proposed Rule, CMS further explains its intention with regard to this change. Under the unamended rule, a therapeutic diet may only be prescribed by the practitioner(s) responsible for the care of the patient. The Interpretive Guidelines in the State Operations Manual (SOM) further explains that "a dietitian may assess a patient's nutritional needs and provide recommendations or consultations for patients, but the patient's diet must be prescribed by the practitioner responsible for the patient's care." 78 Fed. Reg. 9222.

The requirement has been applied "to mean that registered dietitians[1] (RDs) cannot be granted privileges by the hospital to order patient diets (or to order necessary laboratory tests to monitor the effectiveness of dietary plans and orders, or to make subsequent modifications to those diets based on the laboratory tests) since these practitioners have never been considered to be among those in the hospital who are 'responsible for the care of the patient.'" 78 Fed. Reg. 9222.

CMS finds fault in the foregoing restrictions, deeming them "too restrictive and [to] lack the reasonable flexibility to allow hospitals to extend these specific privileges to RDs in accordance with State laws." CMS expresses the notion that RDs are "the professionals who are best qualified to assess a patient's nutritional status and to design and implement a nutritional treatment plan in consultation with the patient's interdisciplinary care team." 78 Fed. Reg. 9222.

CMS intends for its rule change to cause RDs to "be viewed . . . as the [interdisciplinary care] team's clinical nutrition expert . . . responsible for a patient's nutritional diagnosis and treatment in light of the patient's medical diagnosis." 78 Fed. Reg. 9222. In particular, RDs would be able to write dietary orders directly without having to "seek out physicians, APRNs, and PAs to write or co-sign dietary orders." 78 Fed. Reg. 9222.

CMS emphasizes that "Physicians, APRNs, and PAs often lack the training and educational background to manage the sometimes complex nutritional needs of patients with the same degree of efficiency and skill as RDs who have benefited from curriculums that devote a significant number of educational hours to this area of medicine." 78 Fed. Reg. 9223.

[1] The Registered Dietitian (RD) credential is not a government-bestowed credential. It is a private credential bestowed by the credentialing arm of the trade association, the Academy of Nutrition and Dietetics (AND) (formerly the American Dietetic Association).

CMS proposes to use the term "qualified dietitian" in its rule change, explaining that "a few States elect not to use the regulatory term 'registered' and choose instead to use the term 'licensed' (or no modifying term at all) . . ." 78 Fed. Reg. 9222.

CMS cites to three studies in support of its conclusion that RDs enhance the quality of nutrition care afforded patients in the hospital: Kinn T. Clinical order writing privileges. Support Line. 2011; 33; 4;3-10; Peterson SJ, Chen Y, Sullican CA, et al. Assessing the influence of registered dietician order-writing privileges on parenteral nutrition use. J AM Diet Assoc. 2010; 110; 1702-1711; Duffy JK, Gray RL, Roberts S, Glanzer SR, Longoria SL. Independent nutrition order writing by registered dietitians reduces complications associated with nutrition support [abstract]. J Am Diet. Assoc. 2008; 108 (suppl 1): A9. 78 Fed. Reg. 9222-9223.

CMS intends for these changes to effect two public interest benefits: (1) to "achieve a higher quality of care for . . . patients by allowing [RDs] to fully and efficiently function as important members of the hospital care team in the role for which they were trained" and (2) to permit realization of "significant cost savings in many of the areas affected by nutritional care." 78 Fed. Reg. 9223.

Summary of CBNS Recommended Change to Proposed Rule

For the reasons explained in detail below, and as supported by the expert affidavits in the Attachments hereto, CBNS respectfully requests that the CMS Proposed Rule, 42 CFR Part 482, Section 482.28(b)(1),(2), be modified to read as follows (CBNS recommended changes appear in italic):

(b) * * *

(1) Individual patient nutritional needs must be met in accordance with recognized dietary practices.

(2) All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian *or qualified nutritionist* as authorized by the medical staff and in accordance with State law.

COMMENTS

A. The Proposed Rule Does Not Fully Align Therapeutic Diet Ordering Capability with the Appropriate Set of Advanced Nutrition Providers

We commend CMS for recognizing the vital role of nutrition and therapeutic diets in the health of our population, and for expanding the universe of those authorized to provide such services. We support these general goals, and submit these comments opposing the current formulation of the Proposed Rule in an effort to help CMS improve the Proposed Rule so that it may effectively and fairly achieve those goals.

By granting regulatory authorization for solely Registered Dietitians to be the primary newly authorized providers of therapeutic diet ordering in hospitals to the exclusion of other, often more qualified nutrition practitioners, the proposed revision to 42 CFR Part 482, Section 482.28(b)(2) would unwittingly expose patients to the risk that certain RDs who lack advanced education, training, and experience in Medical Nutrition Therapy and therapeutic diet ordering will become "the [interdisciplinary care] team's clinical nutrition expert . . . responsible for a patient's nutritional diagnosis and treatment in light of the patient's medical diagnosis." It likewise excludes the many non-RD nutritionists who have far more advanced training in Medical Nutrition Therapy and therapeutic diets, depriving patients of the benefit of a larger pool of more advanced practitioners.

To ensure achievement of the dual CMS goals of higher quality of patient care and significant cost savings in nutrition care, CBNS respectfully requests that CMS modify Proposed Rule 42 CFR Part 482, Section 482.28(b)(2) to insert "or qualified nutritionist" immediately after the term "qualified dietitian" and before the remainder of the Proposed Rule language. By doing so, CMS will correct an apparently unintended effect of excluding from the scope of the rule nutrition practitioners with graduate level degrees and superior training and experience who have pursued a different route than the private RD credential, and yet are recognized by the states under the same qualifying laws as the RD.

The Registered Dietitian (RD) credential is not a government-bestowed credential. It is a private credential bestowed by the credentialing arm of the trade association, the Academy of Nutrition and Dietetics (AND) (formerly the American Dietetic Association). *See* Exhibit 4 (Decl. of M. Stroka). Only nineteen states effectively require the RD credential or similar dietetics training to legally practice nutrition and dietetics. Fifteen states grant nutritionists state-recognized licensure or certification for the practice of dietetics and nutrition. Twenty-six states do not legally require government-recognized status for the practice of nutrition and dietetics (some states fall into multiple categories). *See id.*

The AND does not require for issuance of its entry-level RD credential the coursework, training and experience in therapeutic diets sufficient to ensure competent and effective therapeutic diets are ordered for patients. *See* Exhibits 1-6. Consequently, while a subset of RDs do in fact independently acquire the necessary education, training and experience to order therapeutic diets competently and effectively, the credential itself provides no assurance of competence in the skill sets needed for "nutritional diagnosis and treatment in light of the patient's medical diagnosis," particularly in management of "the sometimes complex nutritional needs of patients."

The problem of inadequate RD education, experience, and training for the provision of Medical Nutrition Therapy has been the subject of critical review from an authority in dietetics education. *See* Skipper, Lewis. Advanced Medical Nutrition Therapy Practice What Are the Future Needs? Nutrition Today. 2007; 42 (Number 5): 200:

> "Currently, accredited dietetics education programs are designed to prepare students for entry level, defined as the first 3 years of practice. The curriculum for these programs typically includes food service, food science, normal nutrition, community nutrition, and nutritional biochemistry in addition to required general education courses. The medical nutrition therapy portion of the dietetics curriculum may be limited to a single undergraduate course. As part of supervised practice, dietetic students may spend as little as 6 to 8 weeks in medical nutrition therapy practice. Despite limited preparation, approximately 80% of entry-level dietitians provide medical nutrition therapy directly to patients."

CBNS is a certifying organization that specifically determines the education, training, and experience requisite for competent, effective provision of clinical nutrition, including Medical Nutrition Therapy. See Exhibit 4 (Decl. of Michael Stroka, JD, MS, CNS, CCN, LDN). Stroka explains that "Complex nutritional issues that are at the heart of Medical Nutrition Therapy and therapeutic diets require an advanced understanding of metabolism and biochemistry in health and disease" not ordinarily obtainable at the undergraduate level of instruction but, rather, through graduate level course instruction at regionally accredited colleges and universities in degree programs. Some examples of such degrees are the following: MS Applied Clinical Nutrition; MS Applied Physiology and Nutrition; PhD Cellular and Molecular Nutrition; MS Diet and Exercise; MSPH Human Nutrition; PhD Medical Nutrition Science; MS Nutrition and Exercise Science; MS, Ph.D. Metabolic Biology; MS Metabolic and Nutritional Medicine; MS Nutritional Biochemistry; MS Nutrition and Functional Medicine; or MS PHD Nutritional Science. *See* Exhibit 4. The nutrition science, medical and legal members of the Board of Directors of the CBNS considers it prudent that a person has graduate level training and passes a rigorous and relevant clinical nutrition Examination to provide competent and reliable medical nutrition therapy and therapeutic diets to patients.

In a September 2012 white paper, the Academy of Nutrition and Dietetics recommended that the academic training for entry-level RDs should be elevated to "a minimum of a graduate degree from an ACEND-accredited program." *See* AND Visioning Report, "Moving Forward – A Vision for the Continuum of Dietetics Education, Credentialing and Practice" (Sep. 5, 2012) (attached as Exhibit 6), at 8. According to the AND, "[t]he enhanced preparation for practice leads to better critical thinking and *a higher quality of care and protection of the public*." *Id.* (emphasis added). AND observed that "[v]irtually all other allied health professions have increased entry-level educational standards beyond the bachelor's degree to either a master's degree or practice doctorate." *Id.* (noting that certain professional organizations are "very concerned about the current level of education for entry into dietetics practice…").

Our Exhibits explain that the RD is an entry-level credential, and identify the education, training and experience components for that credential and why those components do not in and of themselves provide a level, degree, quality or quantity of education, training, and experience needed for reliably competent and effective ordering of therapeutic diets and Medical Nutrition Therapy.

In Exhibit 2, Stanley Dudrick, MD, CNS explains that "the discipline of nutrition care and nutrition support encompasses a broad field of education and training of qualified nutritionists whose training often goes beyond that of the RD." Dr. Dudrick is one of the world's foremost experts in Medical Nutrition Therapy and therapeutic diets. He is widely recognized and respected throughout the scientific, academic and clinical world for his innovative and pioneering research in the development of the specialized central venous feeding technique known as intravenous hyperalimentation (IVH) or total parenteral nutrition (TPN). The basic investigative development and subsequent successful clinical application of this highly effective therapeutic modality has been described as one of the four most significant accomplishments in the history of the development of modern surgery, together with the discovery and development of asepsis and antisepsis, antibiotic therapy and anesthesia (JAMA 239:192, 1978). It has also been acknowledged as one of the three most important advancements in surgery during the past century along with open heart surgery and organ transplantation. *See* Exhibit 2.

In Exhibit 1, Jeffrey B. Blumberg, PhD, FACN, FASN, CNS, the Senior Scientist and Director of the Antioxidants Research Laboratory at the Jean Mayer USDA Human Nutrition Center on Aging at Tufts University and Professor in the Friedman School of Nutrition Science and Policy and in the Department of Pharmacology and Experimental Therapeutics in the Sackler School of Graduate Biomedical Sciences at Tufts University, likewise explains that a Certified Nutrition Specialist (i.e., the graduate level education, training, examination and experience certification of the CBNS) is that level of academic and experiential accomplishment he regards as "requisite education and training to address common disease states requiring

hospitalization that beget specific nutritional needs, the provision of which would call for acumen based on biochemistry, pharmacology, and nutrition science." *See* Exhibit 1.

In Exhibit 3, Sidney Stohs, PhD, FACN, CNS, ATSF, the Dean Emeritus of the School of Pharmacy and Health Professions, Creighton University Medical Center, and President of CBNS explains: "Provision of Medical Nutrition Therapy, for those patients who are acutely ill and nutritionally compromised, requires advanced skill based on a high level of proficiency based in nutrition science, biochemistry and an understanding of pharmacology as it relates to nutrition. It would be unusual for this proficiency to be obtained at a Bachelor degree level and, therefore, only with the greatest of cautions should the writing of therapeutic diet orders be awarded solely on the basis of attainment of this level of education, whatever the credential. Nutrition Professionals with training backgrounds other than Dietetics who have attained the Certified Nutrition Specialist credential have Masters and/or Doctoral level education in these advanced proficiencies, as these areas are almost the entire focus of education."

As CBNS reads the Proposed Rule, it qualifies RD therapeutic diet ordering privileges with the caveat, "as authorized by the medical staff," suggesting that the medical staff retains the power to determine in an individual case whether a particular practitioner may order therapeutic diets. We ask CMS in the final rule to clarify this point, making it clear that the medical staff should have the flexibility to determine the appropriate education, training, and experience of individual dietitians and nutritionists when authorizing ordering privileges. In that way, an essential independent evaluation of competence will be obtained, enabling medical staff to grant authorization to those who have acquired the requisite level, degree, quality, and quantity of education, training and experience. That clarification, while necessary, is not sufficient because, as currently worded, the proposed limitation of therapeutic diet ordering authorization to "qualified dietitians" presumably excludes nutritionists who possess the requisite education, training, and experience to provide competent and reliable therapeutic diet ordering.

The CMS Proposal to limit therapeutic diet ordering privileges to RDs in the hospital setting conflicts with prior regulatory actions by CMS that have been consistently inclusive of non-RD nutrition professionals. In prior regulations, CMS has repeatedly recognized that "nutrition professionals" are qualified to provide therapeutic dietary care. For instance, here the Proposed Rule is at odds with prior regulations where CMS provided reimbursement under Medicare Part B for Medical Nutrition Therapies. *See* 42 CFR 410.134. The proposed revision here is arbitrary and capricious because CMS, by liming hospital privileges to RDs only, fails to consider the existence of other qualified nutritional professionals, and departs from prior agency policies without a reasoned explanation.

In a May 2012 rulemaking, CMS published a final rule revising the requirements that hospitals and critical access hospitals must meet to participate in Medicare programs. *See*

Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation, 77 Fed. Reg. 29034-01 (May 16, 2012). Those revisions included a proposal to revise CoP in 42 CFR 482.22 concerning the hospital's "medical staff." *Id.* at 29045. CMS considered whether to include "registered dietitians" among those non-physician practitioners who could be appointed to the hospital's medical staff. *Id.* at 29046. CMS refused to name specific credentials, and explained that because "[t]he current requirements … are written to allow a hospital's governing body the greatest flexibility in determining which categories of non-physician practitioners that it chooses to be eligible for appointment to the medical staff." *Id.* at 29047. According to CMS, the hospital had authority "to determine[] which categories are eligible for appointment" and "the final rule … ensure[d] that the medical staff examines the credentials of all eligible candidates…" *Id.* (noting that the rule "is intended to encourage hospitals to be inclusive when they determine which categories of non-physician practitioners will be eligible for appointment to their medical staff").

Agency regulations that concern the same subject matter should be read and construed *in pari material*. *See Erlenbach v. United States*, 409 U.S. 239, 243 (1972) (statutes addressing the same subject matter generally should be read "as if they were one law"). Where agency action reverses or conflicts with prior policy, a court will apply greater scrutiny. *See Center for Science in the Public Interest v. Department of the Treasury*, 573 F. Supp. 1168 (D.D.C. 1983), *vacated in part*, 727 F.2d 1161, 1172 (D.C. Cir. 1984). In Section 410.134, CMS specifically authorizes both qualified "dietitians" and "nutrition professionals" to provide Medical Nutrition Therapy. *See* 42 CFR 410.134. CMS thus determined that qualified dietitians are equally competent to provide those services as nutrition professionals. Yet CMS now provides hospital privileges only to RDs for the same services. That course would be directly at odds with CMS's prior regulations. Moreover, the Proposed Rule would ignore the material differences and similarities between registered dietitians and other qualified nutrition professionals. CMS thereby "entirely fail[s] to consider an important aspect" of the matter. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also Mt. Diablo Hosp. v. Shalala*, 3 F.3d 1226, 1232 (9th Cir. 1993) (agency actions will not be sustained where the agency failed to consider significant alternatives).

B. The Proposed Rule Excludes Those Who Have Requisite Competence from Ordering Therapeutic Diets

By emphasizing RDs as the providers of therapeutic diets under Title 42, the Proposed Rule is both overinclusive (authorizing all RDs, including those with inadequate education, training and experience, to order therapeutic diets) and underinclusive (excluding all who are not Registered Dietitians but who possess graduate level education and requisite training and experience from ordering therapeutic diets). To provide patients optimal care, CBNS urges

CMS to assure a reasonable fit between the means chosen and the ends desired through two distinct remedial actions, designed to perfect the rule proposal.

The AND is advocating for the position that "qualified dietitian" be defined to mean only those with their private trade association's credential "Registered Dietitian." In a February 15, 2013 letter seeking support for this Proposed Rule, the AND stated that their model letter: *"asks CMS to clarify its definition of "qualified dietitian" to comport with that in 42 CFR 482.94(e) ("A qualified dietitian is an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration [AND's credentialing arm].")."*

This suggests the AND is attempting to restrict the benefits of the Proposed Rule solely to members of its private trade association, to the exclusion of other, often more highly qualified practitioners. Such a restriction of benefits to members of one private trade association would directly contradict the guidance of Executive Order 13563, "Improving Regulations and Regulatory Review", in which the President encourages a regulatory framework designed to promote economic growth, innovation, job-creation, and competitiveness. Artificially restricting providers of therapeutic diets to members of one private trade association would create a distinctly anti-competitive and inefficient environment.

Of note, CMS has expressed its broad deference to state licensing laws and regulations regarding qualifications of providers. In its ruling Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation Federal Register/ Vol. 77, No. 95 / Wednesday, May 16, 2012 / Rules and Regulations, CMS states:

> "As we stated in a recent rule addressing credentialing and privileging and telemedicine services, 'CMS recognizes that practitioner licensure laws and regulations have traditionally been, and continue to be, the provenance of individual States, and we are not seeking to pre-empt State authority in this matter.'"

First, CBNS urges CMS to modify the Proposed Rule to insert after the term "qualified dietitian" the phrase "or qualified nutritionist". CBNS further urges CMS to explain that this change is meant to ensure that all of the following will be permitted to order therapeutic diets and function in all respects on a par with qualified dietitians under 42 CFR Part 482:

- those who possess state-granted licensure or certification as a dietitian, nutritionist, or dietitian nutritionist;
- those who possess the Certified Nutrition Specialist credential; and

- those who possess an advanced degree from regionally accredited (the gold standard) colleges and universities in the appropriate fields (for example, MS Applied Clinical Nutrition; MS Applied Physiology and Nutrition; PhD Cellular and Molecular Nutrition; MS Diet and Exercise; MSPH Human Nutrition; PhD Medical Nutrition Science; MS Nutrition and Exercise Science; MS PhD Metabolic Biology; MS Metabolic and Nutritional Medicine; MS Nutritional Biochemistry; MS Nutrition and Functional Medicine; or MS PhD Nutritional Science), demonstrate sufficient practice experience, and demonstrate knowledge by passing a clinically relevant nutrition science and therapy exam.

Second, CBNS urges CMS to emphasize in the Final Rule that the phrase in the existing Proposed Rule "as authorized by the medical staff" be clarified, making it clear that the medical staff should have the flexibility to determine the appropriate education, training, and experience of individual dietitians and nutritionists when authorizing ordering privileges. In that way, an essential independent evaluation of competence will be obtained, enabling medical staff to grant authorization to those who have acquired the requisite level, degree, quality, and quantity of education, training and experience.

By making those two changes manifest in the Final Rule, CMS will ensure that quality care is not compromised and will permit cost savings as the provision of competent and effective therapeutic diet care is maximized. The two changes will thus ensure a reasonable fit between CMS's means and ends, with the added benefit of increasing the universe and quality of health professionals available for these vital positions.

Finally, while the Proposed Rule deals specifically with hospitals, our recommendations for improvement of the Proposed Rule extend to non-hospital facilities, such as long term care facilities, transplant centers and other facilities

CONCLUSION

CBNS respectfully requests that the CMS Proposed Rule, 42 CFR Part 482, Section 482.28(b)(1),(2), be modified to read as follows (CBNS recommended changes appear in italic):

(b) * * *

(1) Individual patient nutritional needs must be met in accordance with recognized dietary practices.

(2) All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified

> dietitian *or qualified nutritionist* as authorized by the medical staff and in accordance with State law.

CBNS further respectfully requests that CMS make clarifications in the Final Rule consistent with our recommendations in Section B above.

Respectfully Submitted,

CERTIFICATION BOARD FOR NUTRITION SPECIALISTS

By Counsel: *__/s/ Jonathan W. Emord__*

Jonathan W. Emord
Peter A. Arhangelsky
EMORD & ASSOCIATES, P.C.
11808 Wolf Run Lane
Clifton, VA 20124
(P) 202-466-6937
(F) 202-318-2381
(e) jemord@emord.com

Dated: April 5, 2013