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Marilynn B. Tavenner, RN
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3244-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

RE: Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation (CMS-3244-P)

Dear Administrator Berwick,

The Academy of Nutrition and Dietetics (formerly the American Dietetic Association, hereinafter the Academy), appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) of the Department of Health and Human Services related to its proposed rule of 24 October 2011 on "Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation" (CMS-3244-P). With over 72,000 members, the Academy is the largest association of food and nutrition professionals in the United States and is committed to improving the nation's health through food and nutrition.

The Academy supports revising requirements for hospitals and critical access hospitals (CAHs) to improve regulations and regulatory review and applauds CMS in reforming, simplifying, and eliminating the unnecessary burden and costs placed on hospitals and CAHs involving registered dietitian services. The Academy seeks specific inclusion of registered dietitians as non-physician practitioners included in and affected by the proposed regulation. In addition, modifications to reduce procedural burden, remove or revise the obsolete, unnecessary and taxing provisions on registered dietitian providers of therapeutic nutrition care, medical nutrition therapies and food services management is most welcomed.

Timely Patient Care

The issue of modification for assessments and medical nutrition therapy

intervention plans based on the initial physician referral and therapeutic diet (nutrition) order remains an obstacle in timely patient-centered care. As detailed below and in the attached article, quality of care is being compromised when the nutrition service delegation to registered dietitians is not accepted as a standard operational procedure and a 24/7 practice within hospitals and CAHs as defined by their governing body.

The statement "[t]here must be an effective governing body that is legally responsible for the conduct of the hospital" applies to hospital nutrition components. As the hospital and multi-hospital systems document demonstrated competency of the registered dietitian in performing the services required to ensure high quality nutrition care, it is the governing body that approves clinical privileges. Granting appropriate clinical privileges to the registered dietitian allows for timely completion of essential components of patient care as ordered by the physician. Registered dietitians meet the criteria in the proposed language creating a new category for those who could be classified as having an associate membership.

Registered dietitians must be permitted to modify and augment the nutrition plan of patients they are following in conjunction with the MD and health care team. Waiting for an MD written/electronic order for routine additions to diet orders inhibits quality and delays patient care. The addition of a nutrition or dietary supplement, modified consistency (chopped, pureed foods due to lack of or missing dentures), thickened liquids to implement plan for a swallowing issues, and simple additional food snacks (*e.g.*, ice cream, peanut butter and jelly sandwich, cheese and crackers) are all examples of appropriate intervention by a registered dietitian that falls within their scope of practice. When the MD/DO orders their registered dietitian to manage Enteral or Parenteral feeding it means the MD/DO expects and intends to delegate the management of the nutrition care process from the consultation, assessment, nutrition diagnosis to the selection of the nutrition product, rate, volume and delivery. The registered dietitian needs to be able to act upon the original order to the fullest extent of his or her scope of practice to ensure the patient timely access to care; waiting for the MD/DO to co-sign orders delays treatment for the patient and causes undue burden on the facility, provider, and patient.

Lack of timely, effective, and patient-centered care proves to not only be economically costly for hospitals and CAHs, but costly to the patient's care. The inequitable and non-communicative nutrition care delivered to the patient can result in nutrition safety and harm situations and inefficiencies across the continuum of care. The transitions of care from the hospital or CAH to an extended, sub acute, home care, rehabilitation, dialysis, or outpatient setting (endocrine/diabetes/weight management), can result in interrupted and inconsistent delivery of medical nutrition therapies due in some states because of regulators' misinterpretation of federal Conditions of Participation and concomitant refusal to allow the clinical privileging of demonstratedly-competent registered dietitians working under the direction of the medical doctor/doctor of osteopathy. In addition, this refusal to properly privilege RDs may increase iatrogenic illnesses

such as malnutrition, weight loss, pressure ulcers, hyper/hypoglycemia related to delays in appropriate nutrition intervention.

State Misinterpretation of CMS Privileging Guidance

Officials from at least one state have prevented dietitians from being part of a hospital's medical staff and obtaining privileges on the premise that CMS regulations require licensure with a disciplinary board for practitioners to be eligible for privileging. ADA seeks clarification and confirmation that CMS regulations neither independently require licensure nor prohibit privileging without licensure or an oversight board. Licensure is not a federal requirement; it is only required for practitioners in those states with laws requiring licensure.[1] Federal regulations specific to dietitians similarly have no independent licensure requirement. In section 482.28(a)(2) of the hospital CoP defining a "qualified dietitian" in the hospital setting, "[q]ualification is determined on the basis of education, experience, specialized training, State licensure or registration *when applicable*, and maintaining professional standards of practice."[2] And in the "Survey Procedures" section of the CoP, surveyors are to "[r]eview the dietitian's personnel file to determine that he/she is qualified based on education, experience, specialized training, and*, if required by State law, is licensed, certified, or registered by the State.*"[3] The fact remains that none of these federal provisions specifically require licensure or certification unless State law—not just a state agency's interpretation of federal regulations—requires licensure or certification. Yet the Academy has found that this premise is evidently misinterpreted by California's Department of Public Health.

In conversations with California state regulators, regulators have not pointed to any provision of state law requiring that dietitians be licensed or certified sufficient to trigger the federal requirement, nor have they directly asserted that CMS requires licensure for all dietitians. Instead, these regulators wholly refuse to condone privileging of dietitians without dietetics licensure because they believe that the CMS Survey and Certification Group Memorandum of 12 November 2004[4] somehow

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[1] Hospital SOM 4482.11 Interpretive Guidance ("All staff that are required by the State to be licensed must possess a current license. The hospital must assure that these personnel are in compliance with the State's licensure laws. The laws requiring licensure vary from state to state. Examples of healthcare professionals that a state may require to be licensed could include: nurses, MD/DOs, physician assistants, dieticians, x-ray technologists, dentists, physical therapists, occupational therapists, respiratory therapists and hospital administrators."). The survey procedures for §482.11(c) confirm that any licensing or certification requirement from CMS is dependent upon an underlying existing state law requirement.

[2] State Operations Manual, Appendix A — Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, accessed 26 November 2010 at www.cms.gov/manuals/Downloads/som107ap_a_hospitals.pdf. (Emphasis added.)

[3] State Operations Manual, Appendix A — Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, accessed 26 November 2010 at www.cms.gov/manuals/Downloads/som107ap_a_hospitals.pdf. (Emphasis added.)

[4] Available November 26, 2010 at http://www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter05-04.pdf.

"implies the need for a state or federal oversight board for practitioners seeking clinical privileging from their hospital's governing body."[5] Specifically, one state regulator mistakenly believes that CMS guidance states that until her state has an established oversight body for hospitals to use for reporting revocation or denial of clinical privileges for Registered Dietitians by an institution's governing body, her surveyors are obligated to cite the hospital as out of compliance with CMS conditions of participation if RDs are practicing as "privileged" providers. She further averred, "Everything requires a primary- or co-signature by the physician."[6]

Such a belief is fundamentally at odds with the CoP revisions here that are intended to eliminate "regulatory impediments [that] may be unduly limiting access to care and/or delaying access to treatment for patients and causing undue burden to practitioners (for example the need to seek out physicians to co-sign orders)." Nothing in CMS regulations or California state law, for example, conclusively precludes thousands of California RDs from becoming privileged by their facilities' governing bodies and medical staff.[7]

Under existing law and regulation, RDs without licensure would naturally lack independent prescriptive authority, but should then be able to become privileged to provide any level of care—including any medical level of care—within their state scope of practice. Nevertheless, all privileging has been effectively stifled by the combination of California regulators' questionable interpretation of CMS regulations. The Academy seeks clarification of guidance related to the revised CoPs here ensuring that qualified RD practitioners can provide timely and quality patient care through hospital governing board oversight and privileging processes.

The registered dietitian employed by or consultant to hospitals and CAHs must be permitted flexibility in completing the patient's nutrition assessment in conjunction with consulting on the nutrition diagnosis with respect to the medical diagnosis. This flexibility leads to designing a best evidence-based practice therapeutic diet recommendation for immediate implementation of the nutrition treatment and intervention plan. The registered dietitian continuously monitors the success or possible revision of the nutrition treatment and intervention plan, which then leads to necessary modifications as determined by the registered dietitian. The patient deserves timely changes in their nutrition as deemed by the registered dietitian.

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[5] *See* "CDA IS CLARIFYING RD PRACTICE ISSUES IN CALIFORNIA," paraphrasing discussion between the California Dietetic Association's Professional Practice Task Force and the California Department of Public Health (CDPH), available November 26, 2011 at www.dietitian.org/member_pdfs/.../LicensureTheBeginning_Nov09.pdf.

[6] Email from Heidi Kiehl to Randi Williams; Government Relations Team; Quality Mgmt Team Mailbox; Richard Curtis; *et al*, 10 June 2009.

[7] Although California has relied exclusively on its interpretation of the CMS memorandum to assert that licensing is required for privileging, the author has identified other support for California's argument that medical staff must be licensed to be privileged. The interpretive guidelines for §482.22(a)(2) require that the medical staff *examine* whether prospective members have certain credentials, including evidence of current licensure, but does not clearly require that the prospective candidate actually *has* the licensure credential.

The Academy appreciates the opportunity to comment on this important initiative; please contact either Jeanne Blankenship at 202-775-8277 ext. 6004 or by email at jblankenship@eatright.org or Pepin Tuma at 202-775-8277 ext. 6001 or by email at ptuma@eatright.org with any questions or requests for additional information.

Sincerely,

Jeanne Blankenship, MS RD
Vice President, Policy Initiatives and Advocacy
American Dietetic Association

Pepin Andrew Tuma, Esq.
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American Dietetic Association

References:

1) Regulatory agencies require that dietitians document nutrition care in the medical record. Therefore, written recommendations in the medical record have become the primary vehicle for communicating with physicians. 44 general hospitals in Philadelphia and the surrounding area were surveyed. Responses were obtained from 35 of the 44 hospitals. Of the 865 recommendations made; 42% were implemented. Higher implementation rates were found for recommendations that were requested by the physician (50%) or discussed with the physician (65%).

   Skipper A, Young M, Rotman N, Nagl H. Physicians' Implementation of Dietitians' Recommendations: A study of effectiveness of dietitians. *Journal of the American Dietetic Association.*1994; 94: 45-49

2) 173 patients were screened and classified as either "at risk for malnutrition" or "not at risk for malnutrition". Of these, 117 were not at risk, 56 were at risk. Median LOS was 4 days for not at risk and 6 days for at risk. Of patients identified as at risk, 91% received nutrition intervention during their stay. In this study, LOS for patients at risk for malnutrition was 50% longer and costs were 36% higher.

   Chima CA, Barco K, Dewitt M, Maeda M, Teran JC, Mullen K. Relationship of nutritional status to length of stay, hospital costs, and discharge status of patients hospitalized in the medicine service. *Journal of the American Dietetic Association.* 1997; 97: 975-978

3) A total of 272 charts documenting care of patients on enteral tube feeding were reviewed. In all cases, the physician wrote the initial order for tube-feeding formulas and rate. Based on an assessment of nutrition needs, the RDs agreed with 21 (8%) of the initial physician orders for enteral nutrition. For the remaining 251 (92%) patients, the RDs recommended changes in the physician's orders. However, physicians implemented the recommendations made by the RD in only 106 (42%) of the cases.
   Physicians' formulations provided approximately 11.5% less energy and 7.8% less protein than recommended by the RD.
   Length of stay for patients whose RD recommendations were followed was significantly shorter than those for whom physician orders were continued (28.5 $\pm$ 1.8 vs 30.5 $\pm$ 4.8 days.

   Braga JM, Hunt A, Pope J, Molaison E. 284 Implementation of Dietitian Recommendations for Enteral Nutrition Results in Improved Outcomes. *Journal of the American Dietetic Association.*2006; 106:281-284

4) Odds of achieving the recommended energy intake goal or increasing or maintaining visceral protein stores were at least 4 times greater when dietitians' recommendations were followed than when they were not.

Weddle DO, Tu NA, Guzik CJ, Ramakrishnan V. Positive association between dietetics recommendations and achievement of enteral nutrition outcomes of care. *Journal of the American Dietetic Association.*1995; 95:753-758

5) In studies involving more than 1327 hospitalized adult patients, 40% to 55% were found to be either malnourished or at risk for malnutrition, and up to 12% were severely malnourished. Surgical patients with likelihood of malnutrition are two to three times more likely to have minor and major complications as well as increased mortality; and their length of stay can be extended by 90% compared with the stay of well-nourished patients. Hospital charges are reported to be from 35-75% higher for malnourished patients than for well-nourished patients. It is not enough to assess patients and identify malnutrition. Outcomes are improved and costs are saved only when appropriate nutrition intervention is given:

   - Patients with abdominal trauma who were fed enterally via jejunostomy had a 4% sepsis rate compared with a 26% rate in patients who received no supplemental nutrition therapy.
   - Patients in a controlled, prospective study of severe head trauma were fed either nasogastrically when bowel sounds returned within 36 hours of injury. Early jejuna feeding reduced length of stay in intensive care 4 days (from 10 days to 6 days) and number of infections (3 vs 14).
   - When supplementary nocturnal tube feeding was given to very thin patients with fracture neck of femur, recuperation time reduced to 16 days (vs 23 days), length of stay reduced to 29 days (vs 38 days) and incident of death was 8% (vs 22%)
   - Management by a nutrition support team resulted in reductions in mortality rate, length of stay, readmission rate, and complications compared with management by nonteam group. A benefit of $4.20 was realized for every $1 invested in the nutrition support team.

   Gallagher-Allred CR, Coble Voss A, Finn SC, McCamish MA. Malnutrition and clinical outcomes: The case for medical nutrition therapy. *Journal of the American Dietetic Association.* 1996; 96:361-369

6) A retrospective cohort was conducted at a single tertiary care urban academic medical center to compare adult Parenteral Nutrition (PN) use before RD order-writing privileges to after RD order writing privileges. Although total hospital admissions increased from the –re-privileges periods, overall PN use decreased from 1080 patients during the pre-privileges period to 885 patients during the post-privileges period. Inappropriate PN use decreased from 482 (45%) to 240 (27%) patients, reflecting a 20% cost savings. RDs with order writing privileges can **decrease inappropriate PN** use and costs in a hospital setting.

   Peterson SJ, Chen Y, Sullivan CA, Kinnare KF, Tupesis NC, Patel GP, Sowa DC, Lateef O, Sheean PM. Assessing the Influence of Registered Dietitian Order-Writing Privileges on Parenteral Nutrition Use *Journal of the American Dietetic Association.* 2010; 110: 1703-1711

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Clinical Order Writing Privileges

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Abstract

Research documenting positive outcomes and significant financial benefits has established the integral role of the registered dietitian (RD) in providing nutrition care. However, such outcomes may not be fully appreciated if RD recommendations are not quickly and effectively applied. Implementing clinical order writing privileges (COWPs) as standard practice for RDs can meet the following goals: provision of patient-centered nutrition care with documentation of improved outcomes and subsequent economic benefits, realization of interdisciplinary patient management, timely patient management when RDs implement Medical Nutrition Therapy (MNT) within 24 hours of identifying a patient as a high nutrition risk compared with delays while awaiting physician consultation, and recognition of RDs as advanced practice professionals. COWPs can be implemented quickly because RDs are well prepared to assume this responsibility through their education process. Annual competency assessment and process evaluations can be completed to assess physician satisfaction with modifications in the privileging process.

Introduction

Health care cost reduction, an increased flexibility in provision of services, and facilitation of optimal use of health care professional resources have driven the case for clinical privileging (1). The Advisory Committee on Consumer Protection and Quality in the Healthcare Industry's Recommendation #4 states that "Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place" (2). Prescriptive authority provides legal recognition that an individual is qualified to provide care as defined by law (3). Because RDs lack prescriptive authority under current state law, physicians have traditionally ordered nutrition care, with RDs providing recommendations for modification of nutrition orders as appropriate. Despite their lack of prescriptive authority, RDs are recognized as the nutrition experts trained to provide MNT and other nutrition services (4). The educational background of RDs includes greater than 50 nutrition-focused core curriculum hours in undergraduate programs and 1,200 hours of supervised practice before eligibility to take the American Dietetic Association (ADA) Commission on Dietetic Registration (CDR) examination (5,6). In contrast, an analysis of data provided by the Clinical Administrative Data Service of the Association of American Medical Colleges found that only 33 accredited United States medical schools (26%) had a required nutrition course (7). The National Research Council identified this deficiency in the United States medical school nutrition education component and recommended that nutrition courses be increased in every United States medical school, with a minimum of 25 hours of core curricular time. However, most nutrition education continues to be taught in the basic science courses and not as a separate nutrition course (8). An estimated shortage of 200,000 physicians by 2020 and an overwhelming number of aging and uninsured citizens as well as an increase in chronic disease will place greater burdens on the health care system in the near future. In addition, an increasing physician workload, provision of health care services in sites where a physician is not available, and recognition of the role of nutrition in disease prevention make implementation of COWPs critical in this era of health care reform (9). With the recognized expertise of RDs in providing nutrition care, instituting *dependent* prescriptive authority through use of COWPs as a part of collaborative interdisciplinary practice can allow RDs to provide nutrition services to meet this health care need (9).

Dependent prescriptive authority occurs when an institution gives RDs consent to write nutrition orders based on pre-established criteria or practice guidelines that have been incorporated into institutional protocols, algorithms, or policies/procedures (10). A recent revised interpretation of regulations by the Centers for Medicare & Medicaid Services (CMS) stating that therapeutic diets must be ordered by the person responsible for the care of the patient has led some institutions to reconsider provision of COWPs through dependent prescriptive authority (11). However, other institutions continue to allow COWPs granted within institution bylaws and after creation of appropriate policies and protocols that allow for specific independent judgments that an institution determines are appropriate for individual health care providers (12). These organizations believe that such an approach protects patients, institutions, and practitioners by clearly identifying the activities that health care providers are qualified and competent to perform.

The specific clinical privileges must be within the RD's professional, state, institution, or individual scope of practice. A general scope of practice is usually developed to identify a specified set of professional activities provided by a given category of professionals and is defined by law in state licensure or certification statutes. The ADA has established a stepwise approach for understanding and using the Scope of Dietetics Practice Framework developed for use by a credentialed dietetics practitioner to perform self-assessment to determine individual scope of practice and what additional education and training may be needed to perform desired functions (13). An individual RD's *legal* scope of practice is determined by the state in which the RD is employed and can vary widely, depending on the state. Legal scope of practice establishes "which professional may provide which health care services, in which settings, and under which guidelines or parameters" (14). Institution-specific competency assessments are important to address the competency of individual RDs despite allowance for COWPS through state guidelines (15).

Use of COWPs can affect other indicators of quality of care, including morbidity and mortality, patient satisfaction, cost

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effectiveness, and patient outcomes (16). Recent elimination of payments to physicians for provision of parenteral nutrition (PN), changes in resident physician work hours, and shortages of clinical pharmacists have reduced the amount of time that physicians can devote to managing PN (9). Although studies have supported financial benefits of RD intervention due to decreased length of stay (9), RDs can also offer financial savings by providing nutrition services at lower costs when compared with physicians (17). As health care reforms push for transition of health services from the inpatient to the outpatient setting, the ability of the RD to implement nutrition care plans efficiently when the physician is not immediately available provides another reason for granting COWPs (3).

These data support the ADA's Scope of Dietetics Practice Framework Subcommittee's Definition of Terms (18) that define how an RD's educational background should support his or her effectiveness at evidence-based nutrition practice and establish recognition of the RD as an institution's clinical nutrition expert. Interdisciplinary team practice, completion of competency assessments, and demonstration of positive outcomes can also provide evidence of the benefits of COWPs. A survey of physicians in an institution using COWPs has demonstrated physician satisfaction (19). All of these factors support the premise that RDs who implement evidence-based practices with COWPs can deliver safe, quality, patient-centered, efficient nutrition care (8).

Historical Perspective

It is important to understand the distinction between prescriptive authority, dependent prescriptive authority, and COWPs. Prescriptive authority is defined by law as the authority to prescribe medications and devices (20). RDs do not have prescriptive authority in any state under current state law. Until RDs can obtain such authority through revision of their licensure acts or attainment of licensure that includes this privilege, use of dependent prescriptive authority via COWPs obtained through adjustment of institution medical staff bylaws and organizational policies and protocols is required.

Clinical privileges have been defined as "authorization granted by the appropriate authority to a practitioner to provide specific care services in an organization within well-defined limits, based on the following factors, as applicable: license, education, training, experience, competence, health status, and judgment" (21). Clinical privileges are a part of a hospital's medical staff bylaws and provide a system to ensure safe, quality patient care by appropriate professionals. Because RDs are considered dependent practitioners, they have traditionally provided health care recommendations and have been unable to write or modify orders directly.

A review of the success other health care professionals in obtaining prescriptive authority and subsequent clinical privileges is important when seeking COWPs. Physicians have traditionally been the primary providers responsible for the outcomes of health care decisions and, as such, have responsibility for the patient's care (22). As a result of a physician shortage in World War II, nurses assumed health care responsibilities that had previously been completed by physicians, which allowed nurses to advance their scope of practice. In the 1950s and 1960s, nurses built on this experience and developed advanced practice positions to help fill gaps in care caused by persistent physician shortages (9). After demonstration of positive outcomes with these additional responsibilities, nurses were able to lobby successfully for prescriptive authority. This led to clinical privileges that have advanced in scope since that time (23).

Other health care professionals have obtained COWPs after modifying their educational program components, allowing advanced practice recognition upon completion of their degrees (9). Registered pharmacy programs were phased out after 2006, and currently all pharmacists graduate with a Doctorate of Pharmacy degree. This advanced level of education allowed clinical pharmacists to obtain limited legal prescriptive authority in 90% of states (9). Physical therapists have been independent practitioners since 1981, when they changed their Code of Ethics and implemented the Doctor of Physical Therapy as the preferred degree for entry-level practice (9). Audiologists, speech therapists, respiratory therapists, and occupational therapists have all attained recognition as independent practitioners via legislation recognized through licensure and scope of practice.

Due to the prescriptive authority within their given scopes of practice, these health care professionals have completed the institutional credentialing process and successfully incorporated COWPs into their practices. However, granting COWPs to other health care professionals does place additional liability on institutions. Therefore, these health care professionals must also regularly demonstrate competency and provide proof of credentials, just as physicians and other health care professionals are required to do (24).

Review of the Literature

Evidence-based dietetics practice is defined as the "use of systematically reviewed scientific evidence in making food and nutrition practice decisions by integrating best available evidence with professional expertise and client values to improve outcomes" (25). In an effort to standardize nutritional guidelines, the ADA published its first evidence-based guidelines in 2001 and developed an online Evidence Analysis Library (EAL) in 2004 that provides dietitians with evidence-based nutrition care guidelines for patient management (26). The ADA EAL process has been recognized as exemplary by The Joint Commission for bringing the best research to practice and has been adapted by the United States Food and Drug Administration to assess the type of qualified health claim that can be listed on a food label (25). This process has also been adopted by the United States Department of Agriculture (USDA) for the development of the Dietary Guidelines for America 2010 and the USDA Nutrition Evidence Library, which is modeled after the EAL. Research has also demonstrated that such evidence-based nutrition care provided by an RD can lead to improved patient outcomes (11,17,19,27–35) . The provision of timely, evidenced-based care is a part of National Patient Safety Goal #2 of The Joint Commission (36). Use of COWPs to accomplish this goal has been demonstrated in the literature (12,17,19,27–45).

Peterson and associates (17) recently conducted a retrospective cohort study of 1,965 patients at a single tertiary-care urban academic medical center to study the influence of the RD with COWPs on appropriate PN usage. Inappropriate PN usage decreased from 482 patients to 240 patients ($P<0.0001$) during the pre and post-COWPs periods, respectively. Their data demonstrated a 20% cost savings in PN usage, which translated to an approximately $300,000 savings to the hospital. This study is the first of its kind to demonstrate that an RD-led nutrition support team could effectively decrease inappropriate PN use, resulting in an additional cost savings.

A study published in abstract form demonstrated the effectiveness of RDs in independent nutrition order writing for PN (27). A total of 190 patients were studied in an acute-care hospital. Those whose PN regimens were ordered by an RD had significantly fewer days of hyperglycemia (57% versus 23%) and fewer days of electrolyte abnormalities (72% versus 39%) compared with patients whose PN regimens were ordered by physicians. RD-managed patients met 85% of their nutrition targets within 48 hours compared with none of the physician-managed patients achieving this goal. The authors suggested that the results demonstrate that RD independent order writing privileges provided safe patient care with improved outcomes.

Use of MNT in a pilot study at an Air Force medical center provides an excellent example of the effectiveness of a COWPs program for RDs (14). In the early 1990s, the Second Report of the Cholesterol Education Program identified the two-step diet to achieve cholesterol reduction. After Step 1 education by the RD, a visit to the physician was required to obtain orders for laboratory follow-up tests and to determine the need for diet change. The RDs in this institution made a compelling case for saving physician time and enhancing patient care if they were allowed to order the cholesterol laboratory tests and be legally responsible for taking appropriate action if the results were abnormal. A protocol was approved and a physician was assigned to oversee the RDs. After a few weeks, the RDs requested permission to apply for COWPs for activities within their scope of practice, including ordering and interpreting selected laboratory tests with continued physician oversight. The pilot served as a basis for expanding the program to include laboratory tests in the RDs' provision of care to patients with diabetes. The program was eventually incorporated into Air Force regulations and COWPs were granted. Every 2 years, a review of care was completed and evaluated by the hospital's Credentials Committee and a determination was made about whether COWPs should be renewed. RDs were incorporated into the Executive Committee of the Medical Staff, allowing them to represent allied health care professionals. Allowing RDs to provide MNT on an outpatient basis with the ability to order laboratory tests and modify interventions based on test results has the potential to reduce the number of physician visits. This system process provides an excellent example of how COWPs can provide a more patient-centered, timely, efficient, effective, safe, and equitable care model in accordance with the Institute of Medicine's six aims for quality health care (2).

The Clinical Privileges for Dietitian Nutrition Order Writing System (CPD NOW) at a long-term acute-care hospital in Arizona provides another example of an effective COWPs program (19). A 1-year review of patients at this facility showed a 65% incidence of malnutrition. Traditionally, after a nutrition assessment was completed by the RD and recommendations were documented in the medical record, physicians were assumed to review and implement the recommendations. However, RDs found recommendations were not being implemented in a *timely* manner. RDs began a time- and labor-intensive process of bringing the recommendations to the physicians' attention. A fourfold increase in physician consultation requests over 5 years before the study led to the assumption that physicians valued the RDs' expertise and recommendations. A chart review of approximately 250 patient records also established that although implementation of recommendations was not timely, physicians followed 95% of the RD recommendations. This suggested a system problem rather than a disagreement with RD recommendations. Therefore, a need to develop a more efficient and effective approach to incorporate RD recommendations was recognized.

The CPD NOW program was developed to allow RDs to implement nutrition care orders immediately, with the primary goals being the provision of appropriate and timely nutrition care and improved patient nutritional status (19). Approval for an RD to write an order into a patient medical record was already specified in the hospital. The development process included informal discussions with hospital administrators, physicians, and other health care staff. Two concerns identified were that not all physicians wanted to participate and nursing administration wanted written documentation of the orders RDs could write. In consultation with the medical director, a preliminary list of accepted orders was refined to a specific list of orders that RDs could write, which subsequently were approved by the other medical staff. Competency requirements for RDs were established that included maintenance of registration as an RD by the CDR of the ADA; certification by the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) National Board of Nutrition Support Certification, Inc, as a Certified Nutrition Support Clinician; demonstrated competency to write orders for PN and enteral nutrition; continued professional education, with emphasis in nutrition support; and employment on staff for a minimum of 6 months (this study was conducted before licensure was mandated). Monitoring and evaluation procedures included overall evaluation of the program annually and 3-month probationary periods initially for each RD, with full COWPs status granted after review by the medical director. Once given full status, RDs were subject to annual performance appraisals. At the initiation of the program, 77% of physicians participated. Within 5 years of implementation, this number increased to 92%. Quality improvement analysis revealed that 75% of patients experienced improvements in nutritional status after implementation of the program compared with 55% before the study. Other benefits included increased recognition of RD expertise and increased RD job satisfaction (19).

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RDs at the Toronto Rehabilitation Institute obtained COWPs after their organization's professional practice portfolio hired a consultant to provide expertise in the implementation of the Regulated Health Professionals Act in Canada (28). This consultant's report identified limitations to successful dietetic practice within the hospital's system. Based on these findings, the consultant held meetings with physicians to improve communication and team functioning. The physician group recognized that patient-centered care would improve if COWPs were implemented and recommended their facility adopt this process. A medical directive was developed and presented to key stakeholders, including nurse practitioners, nurse educators, speech therapists, the Clinical Practice Committee, and the Medical Advisory Committee. Quality monitoring mechanisms and supporting documentation were defined, with ongoing evaluation incorporated.

The RDs expanded their COWPs program and were authorized through a medical directive to prescribe multiple vitamins with minerals (MVWMs) and to discontinue orders for unnecessary MVWMs (29). Current literature provides poor direction on the efficacy and safety of MVWMs for adults with medical conditions, despite the high prevalence of their use to prevent or treat chronic disease. Therefore, the RDs at this facility conducted a comprehensive literature review to test the strength of evidence for use of MVWMs and determine its relevance to specific populations. The evidence-based answers provided a framework used by these RDs to prescribe MVWMs. This resulted in a reduction in the fragmentation of patient care and expanded on the previous medical directive that authorized these RDs to write diet and tube feeding orders, enabling them to order complete nutrition therapy. Multiple other studies have documented the positive outcomes associated with RD provision of MNT (30–35).

These studies clearly demonstrate the positive outcomes that the COWPs program offers for patients, RDs, and other key stakeholders. In addition, regulatory and quality agencies mandate effective interdisciplinary communication practices to achieve these outcomes. The Advisory Committee on Consumer Protection and Quality in the Health Care Industry's Recommendation #4 (2) has identified health care professionals' communication of recommendations as an initiative. Facilitation of the RD's role as a vital member of the interdisciplinary team can be enhanced by implementation of COWPs (34). Moreland and associates (19) surveyed physician satisfaction with the COWPs program after it was in place for 2 years and demonstrated 100% physician satisfaction with the service. The physicians stated that the nutritional status of their patients benefited from COWPs, that the system provided sufficient safeguards for patient health and physician liability, and that the system met their needs. This study provides evidence that RDs with COWPs can overcome traditional models of care and demonstrate positive outcomes, in addition to expediting order implementation in a teaching hospital environment.

Reimbursement for MNT and nutrition education of patients with diabetes or renal disease is provided under CMS guidelines and by some private insurers (37). Therefore, appropriate initiation of therapy when recognized by the RD can provide an economic benefit to the institution. This also helps fulfill the mission of health care organizations that are redesigning systems to maximize efficiency and safety by using professionals with appropriate skill sets. A study in the *New England Journal of Medicine* demonstrated the trend of patients to use non-physician health care providers for preventive care (38). Such care often includes nutrition information, recognizing the role of nutrition in disease prevention that is often provided in a nontraditional setting that is more convenient to the patient and in which physicians may not normally be present. These data suggest that by implementing COWPs, physicians can focus their attention on medical therapies, allowing for more effective use of health care resources (38).

Cost Benefit

The ADA EAL demonstrates Grade I evidence of improved clinical outcomes and reduced costs with the provision of outpatient MNT relative to physician time, medication use, and/or hospital admissions in obesity, diabetes, disorders of lipid metabolism, and chronic disease (39). Grades are assigned to indicate the overall strength or weakness of evidence in forming the conclusion statement. Grade I means there is good evidence supporting the statement, Grade II indicates fair evidence, Grade III evidence is limited, Grade IV represents expert opinion, and Grade V is evidence that is not assignable (40). Grade 2 evidence suggests a cost benefit of inpatient RD services (40). Use of these data as well as cost-benefit and cost-effectiveness tools that measure efficiency, effectiveness, reduced errors, improved outcomes, labor costs, and costs associated with treatments resulting from inappropriate nutrition orders are critical to include when presenting a COWPs proposal to an institution (7).

Regulatory Guidelines

Although ample evidence demonstrates the cost effectiveness of COWPs, professionals must also identify and understand five essential components of the COWPs process before requesting privileges: federal regulations, state facility licensing regulations, voluntary accreditation standards, state occupational regulations, and facility policies and procedures.

Federal regulations regarding COWPs are provided by CMS. As mentioned previously in this article, a recent white paper released by CMS regarding interpretative guideline 42 CFR §482.28 (b)(1) states, "therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients." CMS interpretative guideline 42 CFR §482.28 (a)(2) clarified the guideline, stating that RD responsibilities include "collaborating with other hospital services (medical staff, nursing services, pharmacy services, social work services) to plan and implement patient care as necessary in meeting the nutrition needs of the patients" as well as "maintaining pertinent patient data necessary to recommend, *prescribe*, or modify therapeutic diets as needed to meet

the nutritional needs of the patient" (41). The interpretive guideline states that RDs can write therapeutic diet orders through the use of governing body-approved protocols, physician delegation of authority to write therapeutic diet orders, and receipt of verbal orders (3). The Joint Commission Standard TX.4.2 Intent reads, "Food and nutrition products are administered only on the prescription or order of a medical staff member or another individual who has been granted clinical privileges to write such prescriptions of order" (42).

Because RD licensure varies from state to state and might include specific language prohibiting COWPs, it is imperative to review state licensure laws before introducing a proposal for COWPs. The ADA Scope of Dietetics Practice, which encompasses the Standards of Practice and Standards of Professional Performance for RDs and Dietetics Technicians–Registered (18) and the A.S.P.E.N. Scope of Practice for Nutrition Support Dietitians (18) can provide guidance during the COWPs (8). If an institution's medical staff bylaws do not delineate policies or procedures for COWPs, RDs need to propose amendments to the bylaws. A hospital's Medical Executive Committee establishes the bylaws, rules, and regulations for medical staff. A primary purpose is to assure delivery of appropriate and safe treatments from credentialed professionals. Once appropriate facility bylaws are in place, protocols and policies are developed that delineate the RD privileges.

Competence

After COWPs have been granted, RDs must maintain appropriate credentials and state licensure, if applicable. Credentialing is defined as "the formal recognition of professional or technical competence recognized by certification and licensure" and is provided by the CDR (11). State licensure authorizes a legal scope of practice, provides legal use of a title, and includes standards of practice. Licensure indicates that an individual has completed eligibility requirements to obtain a title and authorizes practice within a defined scope. The primary purpose of licensure is public protection and safety (43). RDs complete a registration examination administered by the CDR, which is also used as the state licensure examination. More than 50% of RDs hold advanced degrees, and many RDs voluntarily complete certification examinations for professional recognition in a specialty area of practice (44). Not only should RDs demonstrate that they have appropriate credentials required for the COWPs requested, but they must also be able to demonstrate clinical competence to the medical staff.

Clinical competence can be demonstrated by a variety of means. As a part of the Nutrition Care Process proposed by the ADA, nutritional diagnostic codes reinforce the independent clinical decision making of dietitians. The nutrition diagnoses may also support the medical diagnosis made by the physician and provide guidelines for specific MNT (8). The provision of MNT with documentation of improved patient outcomes as demonstrated through medical record audits; competency examinations; specialty certifications such as in nutrition support (CNSC), diabetes education (CDE), and pediatric nutrition (CSP); publication of research in peer-reviewed journals; professional presentations at national association meetings; and institution-specific evaluation tools can serve as evidence of required clinical expertise. The A.S.P.E.N. Standards of Practice for Nutrition Support Dietitians states: "[Nutrition support dietitians] may recommend, write orders, or obtain verbal orders for enteral and parenteral formulations (as guided by professional licensure or delineated by clinical privileges of an institution)" (45). Other examples of advanced practice skills for RDs include indirect calorimetry measurement, enteral feeding tube placement (46), catheter and enteral feeding tube device care (46), and insulin teaching (47). Use of the ADA Scope of Dietetics Practice Framework is essential to determine an individual's competencies and the need for further professional development (48).

Developing a Proposal

Development of a proposal to request COWPs begins with completion of a needs assessment and an understanding of the culture of the specific institution's environment. Using the ADA Scope of Dietetics Practice Framework, RDs may determine their ability to perform desired functions, which involves review of their legal scope of practice delineated in state licensure statutes, rules, and regulations. Knowledge of both internal and external legal and regulatory environments as well as a current review of the literature can support such a needs assessment. Determination of the hospital's policies and procedures for credentialing non-physician professionals and subsequent training that might be required to meet accreditation standards can help identify education, training, credentials, experience, and demonstrated competency needed. Additional staffing requirements following adjustment of RD responsibilities as a result of the implementation of COWPs should be included. A meeting with risk management and quality management personnel and a review of regulatory guidelines can assure compliance with mandates. After these steps have been completed, a proposal (sample available in Appendix A) providing the rationale of how COWPs can provide safe, patient-centered, timely, cost-efficient, quality nutrition care as well as plans for ongoing competency assessment (Appendix B) should be presented to the organization (43).

Implementation

Understanding and addressing the reactions of both RDs and other health care professionals to the changes inherent in the implementation of COWPs is key to long-term success. Bridges Theory of Transitions appears to fit the process of change that should be associated with implementation of COWPs (49). It is critical to address change issues with COWPs implementation to optimize program effectiveness.

Incorporation of appropriate educational preparation allows for an easier transition to change during COWP implementation. Experienced or advanced practice RNs, RDs, and members of the medical staff can provide mentoring for those RDs implementing the COWPs process. Completion of graduate level education, certifications, or specialized training; participation in interdisciplinary rounds that include nutrition-focused

(Continued on next page)

physical assessment; precepting of dietetic students and/or teaching in a classroom; review of literature; development of research studies to assess outcomes measurement; and participation in advanced-level continuing education activities can help assure advanced practice competency and ability to assume COWPs (45). The adjustment of undergraduate dietetic education curricula to meet these criteria would allow RDs to assume advanced practice roles with COWPs more easily.

Summary

Cost-effectiveness, clinical outcomes, and patient perceptions as a result of implementation of COWPs should continue to provide opportunities for research (11). It is critical for RDs, physicians, and hospitals to seize this opportunity to provide patient-centered, timely, evidence-based care through the COWPs program. It is possible that COWPs will promote positive outcomes while improving the nutritional status, functionality, health, and quality of life of patients. Use of COWPs in conjunction with participation on an interdisciplinary team can promote process improvements, cost savings, and timely patient services. Decreased health care labor costs ultimately should translate into value for the patient and the health care organization. COWPs also can result in improved job satisfaction for RDs.

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Appendix A. Sample Proposal for Requesting Clinical Order Writing Privilege

Goals

1. Dietitians will deliver expert, patient-centered nutrition care via implementation of clinical order writing privileges (COWPs).
2. Nutrition care provided by dietitians will improve the quality of patient care, demonstrating improved outcomes, including decreased implementation times for diet order changes and oral supplement initiation, as demonstrated through research studies during the trial phase.
3. This initiative will promote interdisciplinary patient management and system processes by realizing Goal #2 of the 2007 National Patient Safety Goals "Improving the effectiveness of communication among caregivers" (Joint Commission on Accreditation of Hospitals, 1995), as documented by achievement of 90% positive rating in physician evaluation survey in June 2009.
4. With incorporation of clinical order writing privileges, dietitians will provide Medical Nutrition Therapy (the assessment of an individual's overall nutrition status followed by an individualized course of treatment to prevent or treat medical illness) within 24 hours of identification of high-risk nutritional status.
5. Dietitians will be the recognized nutrition experts through implementation of this advanced practice initiative.

Objectives

To reach these goals, clinical management and staff dietitians will:

1. Conduct a needs assessment to determine how COWPs are used within the current organizational structure and how COWPs for dietitians can enhance patient safety and quality of care.
2. Obtain, read, and understand the following:
   - Federal regulations that provide the nationwide minimum standards for safe and quality patient care
   - State regulations, including both occupational regulation of dietetic practitioners and nutritionists (state licensure, registration, or certification) and health care facility licensing regulations
   - Accreditation standards, if applicable
   - Health care facility workplace policies and procedures
3. Determine the unwritten culture of the facility and its ability to sustain new procedures.
4. Assess the competence and skills of the dietetic staff to write diet orders or other procedures that may require facility-granted privileges.
5. Have the clinical director construct COWPs policy and procedure and outcomes measurement tools and distribute them to appropriate hospital administration, physician leaders, and committees for review and approval. Specific procedures include type of orders that may be written, privileging criteria, timing/manner/unit in which orders may be written, outcome measures, procedures for cosignature
6. Have dietetic staff complete competency assessment before receiving COWPs. Criteria will be set for continuing education requirements necessary to maintain COWPs, and competency assessment will take place on a biannual basis.
7. Conduct a trial of COWPs process in areas agreed upon by medical and nutrition staff. Outcome measure instruments will be developed to assess benefits of COWPs program.
8. Have evaluation surveys discussing effectiveness of the system processes completed by physician, nutrition, and other staff, as appropriate.

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Appendix B. Evaluation Plan

Physician evaluation will take place after the trial phase and annually thereafter with the following instrument. This tool will be modified for other key stakeholder evaluations, if needed. Dietitian satisfaction will be evaluated monthly at staff meetings.

CLINICAL PRIVILEGES FOR DIETITIANS- PHYSICIAN SATISFACTION SURVEY

Survey Question	Response		
1. Are you satisfied with this service?	Yes	No	Neutral
2. Has the nutritional status of your patients benefited from this service?	Yes	No	Neutral
3. Has the service saved you time?	Yes	No	Neutral
4. Would you like this service to continue?	Yes	No	Neutral
5. Do you feel the current system has adequate safeguards for patient health and physician liability?	Yes	No	Neutral
6. Does the current system meet your needs?	Yes	No	Neutral
7. Are you comfortable when you see dietitians writing orders on patient charts?	Yes	No	Neutral

Suggestions for improvement

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