December 26, 2012

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244–8010

Re: CMS–9980–P (Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation)

The Academy of Nutrition and Dietetics (the “Academy”), formerly the American Dietetic Association, is pleased to comment on proposed rule “Patient Protection and Affordable Care Act (ACA); Standards Related to Essential Health Benefits (EHB), Actuarial Value, and Accreditation” (CMS-9980-P) issued November 26, 2012. The Academy is the world’s largest organization of food and nutrition professionals, with more than 73,000 members comprised of registered dietitians (RDs), dietetic technicians, registered, and advanced-degree nutritionists. Every day we work with Americans in all walks of life—from birth through old age—providing nutrition care. We are committed to improving the nation’s health through food and nutrition and providing medical nutrition therapy (MNT)¹ and other evidence-based nutrition counseling services that meet the health needs of all citizens. The Academy generally supports the framework of the proposed rule and offers the below comments related to specific provisions thereof.

Oversight of Base-Benchmark Plan Selection
The Academy recognizes the need to define the EHB flexibly and somewhat less prescriptively to allow benefits to appropriately evolve with emerging science and consumer health needs. Accordingly, the Secretary of the Department of Health and Human Services (the “Secretary,” “HHS”) should ensure adequate federal oversight of benchmark plan selection to reflect the vital and unique role that nutrition plays in improving and maintaining the health of all Americans. Specifically, the Academy supports a frequent timeline for updates to the EHB, with updates every year after the initial two-year timeline proposed in the rule.

Review of the selected base-benchmark plans and default benchmark plans in the appendix to the proposed rule confirms a troubling inconsistency and ambiguity in states’ coverage

¹ Medical nutrition therapy (MNT) is an evidence-based application of the Nutrition Care Process. According the Academy’s definition, the provision of MNT (to a patient/client) may include one or more of the following: nutrition assessment/ re-assessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation that typically results in the prevention, delay or management of diseases and/or conditions. [Academy of Nutrition and Dietetics. Definition of Terms List. Available at http://www.eatright.org/scope/. Accessed December, 17 2012.] The term MNT is sometimes used interchangeably with, but is sometimes considered different from, nutrition counseling in health insurance plans. Further, the Academy’s definition of MNT is broader than the definition of MNT in the Social Security Act (42 U.S.C. 1395vv(1)).
for both MNT and other nutrition services. This ambiguity and inconsistency necessitates aggressive oversight of state base-benchmark plan selections by HHS to ensure inclusion of each of the various types of nutrition services that should included in EHB-benchmark plans. While health plans may include specific benefit language related to MNT and/or nutrition counseling, terminology and actual coverage for these nutrition services are not as consistently and explicitly detailed as that of other specialist services, such as physician specialists and physical/occupational/speech therapy services. Therefore, because both health plans and consumers would benefit from greater specificity of MNT in the listed elements of the EHB, HHS should specifically determine whether a base benchmark plan meets the required minimum coverage of MNT and other nutrition services. HHS must provide this additional guidance to states to clarify the extent of nutrition services that HHS requires prior to approving states’ EHB-benchmark plans.

As an example, HHS’s failure to include any specificity or explicit definitions of what must be included in preventive and wellness services and chronic disease management led North Dakota to choose the single potential base-benchmark plan that appears on its face to lack coverage of cost-effective, clinically effective MNT for consumers. As a result, unless HHS acts, North Dakotans with anorexia, bulimia, chronic renal failure, gestational diabetes, celiac disease, hyperlipidemia, hypertension, obesity and phenylketonuria will not get the chronic disease management they require. Any HHS-approved EHB-benchmark plan must include these critical services.

We also support the requirement “that a health insurance issuer that offers health insurance coverage in the individual or small group market—inside or outside of the Exchange—ensure that such coverage offers the EHB package, thereby providing consistency for consumers who move in and out of the Exchange.” The Academy believes that consistency and transparency among issuers in essential benefits will benefit consumers seeking insurance by enabling them to easily compare plans and make informed choices. We also support the proposal that multi-state plans must meet benchmark standards set by OPM and look forward to clarification and guidance ensuring the inclusion of nutrition counseling and medical nutrition therapy in approved multi-state plans.

Clarifying Ambiguity in EHB Categories
The Academy believes access to quality care is a right that must be extended to all Americans, but the promise of access and quality care is threatened by the vague and ill-defined nature of some of the EHB categories. Four of the top six leading causes of death can be influenced and ameliorated by cost-effective nutrition and diet counseling and interventions by registered dietitians. If health care reform is going to be successful, then the EHB must include services that demonstrably improve the nutritional status of Americans and reduce the rates of obesity, cardiovascular disease, renal disease, hypertension, diabetes, HIV, forms of cancer, celiac disease, stroke, and other medical conditions. As detailed in the MNT Effectiveness Project published in the Academy’s Evidence Analysis Library, MNT and other evidence-based nutrition services, from pre-conception through end-of-life, are an essential component of comprehensive health care,
whether provided as frontline therapy to prevent disease, delay disease progression, or as an intervention in chronic care management.²

Numerous national clinical practice guidelines for the management of chronic diseases such as those for cardiovascular disease, diabetes and hypertension include a nutrition component and recommend referrals to registered dietitians for their recognized expertise in delivering these services.³ A lack of coverage—or ambiguous benefit categories that may permit a lack of coverage—for comprehensive nutrition counseling and behavioral interventions will simply shift care to pharmacological agents and other more invasive and costly modalities. Efforts to provide the nutrition component entirely through diet handouts without the accompanying professional service have been proven unsuccessful and a poor substitute for MNT. The Academy urges the Secretary to recognize that the goals of balancing affordability with providing covered benefits equal to those under a typical employer plan can best be achieved by including medically necessary, evidence-based MNT and nutrition counseling services under ACA Sections 1302(b)(1)(A) (ambulatory patient services), (b)(1)(c) (hospitalization services), (b)(1)(D) (maternity and newborn care), (b)(1)(G) rehabilitative and habilitative services and devices, (b)(1)(I) (preventive and wellness services and chronic disease management), and (b)(1)(J) (pediatric services).

The Academy questions the proposal to exclude specific benefits from EHB coverage, specifically long-term/custodial nursing home care, non-pediatric dental services, and routine eye exams and services. The proposed rule indicates that the basis for the proposed exclusion is that they “often qualify as excepted benefits,” citing inter alia 26 CFR 54.9831-1 (“Limited-scope dental benefits, limited-scope vision benefits, or long-term care benefits are excepted if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of a group health plan as described in paragraph (c)(3)(ii) of this section.”) (Emphasis added). Long-term/custodial nursing home care is a valuable and important benefit relied upon by many citizens. Further, poor dentition makes it difficult to eat nutritious meals and poor eyesight prevents patients from easily reading and following pharmacy and discharge instructions. Accordingly, the Academy seeks clarification on the basis for the proposed exclusion and inclusion of these specific benefits given that the conditional rationale for exclusion provided in the cited federal regulations does not appear to be applicable here.

The Academy additionally seeks clarification whether nutrition counseling and psychiatric/psychological counseling for eating disorders will be covered under the mental

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² Grade 1 data. ADA Evidence Analysis Library, http://www.adaevidencylibrary.com/topic.cfm?cat=3949. [Grade Definitions: Strength of the Evidence for a Conclusion/Recommendation Grade I, “Good evidence is defined as: “The evidence consists of results from studies of strong design for answering the questions addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias and flaws in research design. Studies with negative results have sufficiently large sample sizes to have adequate statistical power.”

health and substance use disorder services category, and if not whether it is included elsewhere as an EHB. The Academy also questions whether the maternity and newborn care EHB category extends WIC-type counseling benefits to those who do not meet current WIC income restrictions given the consistently cost-saving outcomes obtained by WIC.

**Preventive and Wellness Services and Chronic Disease Management**

Section 1302(b)(1)(I) (preventive and wellness services and chronic disease management) is perhaps the least well defined element of the ten EHB listed in the ACA, the Institute of Medicine (IOM) recommendations, and the insurance market. For too long, our nation’s health policy has not been focused on disease prevention, wellness, and healthy lifestyles, and the ACA was largely intended to change that emphasis. Although nearly half of the people in the United States suffer from preventable chronic conditions, relatively few resources have been committed to the broad array of potential solutions that influence whether and how individuals choose to achieve and maintain health. Preventive and wellness services cannot be limited to adult physical examinations and well-baby care. For example, RD-provided MNT for pre-diabetes has been shown to cost-effectively prevent onset of Type 2 diabetes.\(^4\) We remain concerned over the lack of specificity surrounding coverage for intensive, multi-component behavioral interventions. The Academy urges that preventive and wellness services as an element of the EHB include all evidence-based interventions shown to work in reducing the risks of developing chronic disease, including referral for behavioral interventions with RDs or other qualified specialists demonstrated to be clinically effective. Services should be covered if they are evidence-based, an otherwise covered category of service, and recommended by the primary care practitioner treating the patient.

Group health plans and health insurance issuers offering group or individual health insurance coverage are required to provide any additional evidence-based items or preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a rating of A or B. The Academy supports explicitly defining at a minimum any nutrition-related preventive services in the EHB as those services encompassed by Section 2713(a) of the ACA. In addition, consistent with HHS’s proposal that “a plan does not provide EHB unless it provides all preventive services described in section 2713[(a)(1)] of the [Public Health Service] Act,” the Academy seeks clarification regarding the interval after which a preventive service rated with an A or B by the USPSTF must be included in a state’s EHB. (Emphasis added.) The Academy encourages the Secretary to establish an interval of no later than the one year minimum specified in Section 2713(b)(1), irrespective of any other timetable HHS chooses for updating the EHB more broadly over time.

The Academy seeks clarification for the process by which USPSTF recommendations will be incorporated into EHB over time and the process for determining the frequency and intensity of covered behavioral interventions. The USPSTF presently recommends three nutrition-related behavioral interventions with an A or B rating: (1) intensive behavioral

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counseling for cardiovascular disease; (2) intensive, multicomponent behavioral interventions for management of obesity; and (3) intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease.\(^5\) The USPSTF’s recommendation for MNT for obesity management notes that “the most effective interventions were comprehensive and were of high intensity (12 to 26 sessions in a year),” but ambiguity in the current base benchmark plans raises questions of the extent to which health plans recognize the necessity of including these services as EHB.\(^6\) To the extent that HHS does not specify the number of covered visits to RD specialists for MNT, national practice guidelines should determine appropriate coverage.

An example of the need to clarify the extent of coverage for USPSTF-recommended services is present in Ohio, where the default benchmark plan (Community Insurance Company/Anthem BCBS) excludes coverage for all obesity treatment services. Such an exclusion both fails to meet the requirement that EHB include all USPSTF recommended services with an A or B rating (such as intensive, multicomponent behavioral interventions for management of obesity) and will likely result in significantly added costs to the system and worsened overall health. To avoid confusion, HHS must clarify the nature and extent of coverage for management of obesity and other chronic diseases.

The Academy supports an expansive definition of “chronic disease” and implementation of whole-population prevention strategies to encourage healthy lifestyles. To that aim and to fulfill the specific intent of Section 1302(b)(4) of the ACA, the EHB should “take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups.” To reduce costs and improve health, it is critical to ensure that the EHB include specific chronic disease management, counseling, and self-care to provide patients of all ages and medical conditions with more knowledge and the tools to improve their health.

**Coverage and Qualified Providers Differ for Various Nutrition Services**

RDs should be designated as the recognized providers of nutrition services, including medical nutrition therapy and nutrition counseling because of RDs’ demonstrated competency and effectiveness. The Social Security Act defines MNT somewhat differently than the Academy, as “nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional . . . pursuant to a referral by a physician.”\(^7\) MNT is thus distinctly different than mere nutrition education\(^8\) or wellness programs and requires the advanced skill set of

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\(^7\) 42 U.S.C. 1395(vv)(1).

\(^8\) The Academy defines nutrition education as “the formal process to instruct or train patient(s)/client(s) in a skill or to impart knowledge to help patient(s)/client(s) voluntarily manage or modify food choices and
specialists such as RDs rather than differently qualified nutritionists, health coaches or primary care physicians without a nutrition background. As noted below, MNT is covered differently in health plans than nutrition education, wellness programs or weight loss services. For example, some base-benchmark plans specifically exclude “weight loss services” (which are usually understood to mean programs like Weight Watchers or Nutrisystem), but include MNT or bariatric surgery as chronic disease management for obesity. Similarly, a general wellness “nutrition counseling” benefit may be limited to two annual visits with an RD or nutrition professional, but MNT for diabetes or end stage renal disease is covered to allow more frequent treatment. We agree with the Institute of Medicine (IOM) that the appropriate distinction for determining the extent of coverage for MNT versus simple nutrition education and wellness services is whether the nutrition-related service provided is medical rather than non-medical. Both nutrition counseling and medical nutrition therapy are well-recognized as medical services, embodied as necessary preventive services by the USPSTF, covered by Medicare and private health insurance plans, and coded by the Current Procedural Terminology, CPT 97802-97804. As further detailed above, the Academy seeks specific clarification that MNT services are included as EHB for chronic disease management upon referral from a physician.

Nutrition counseling is medically necessary for chronic disease states in which dietary adjustment has a therapeutic role, when it is prescribed by a physician and furnished by a qualified provider. The most appropriate and accepted definition for qualified providers of medically necessary intensive behavioral and dietary counseling is limited to a registered dietitian, qualified nutrition professional, or other qualified licensed health professional (such as nurse practitioners or physicians who are trained in nutrition) recognized under the Social Security Act. HHS should designate the qualified, credentialed provider of nutrition care services that go beyond “wellness” and provision of general non-medical nutrition information or weight-loss services as consistent with the Social Security Act definition to ensure clinically effective care that protects the public’s health.

eating behavior to maintain or improve health.” Academy of Nutrition and Dietetics. Definition of Terms List. Available at http://www.eatright.org/scope/, accessed December 24, 2012.


10 42 U.S.C. 1395(vv)(2) (“[T]he term ‘registered dietitian or nutrition professional’ means an individual who—

(A) holds a baccalaureate or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized by the Secretary for this purpose;

(B) has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and

(C) (i) is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed; or

(ii) in the case of an individual in a State that does not provide for such licensure or certification, meets such other criteria as the Secretary establishes.

11 42 U.S.C. 1395u(c)18(C).
RDs remain the most cost-effective, qualified healthcare professional to provide nutrition based lifestyle interventions, including MNT and evidence-based nutrition counseling and weight-loss management services. RDs have demonstrated competencies and outcomes that differently and less qualified providers of non-medical nutrition services have been yet unable to demonstrate. RDs’ evidence-based national practice guidelines and Evidence Analysis Library are leading, respected tools for effecting positive health outcomes. According to the 2000 IOM report, “The Role of Nutrition in Maintaining Health in the Nation’s Elderly,” both physicians and registered dietitians may provide nutrition services. The IOM found that “the registered dietitian is currently the single identifiable group of health-care professionals with standardized education, clinical training, continuing education and national credentialing requirements necessary to be directly reimbursed as a provider of nutrition therapy.” A just-published article in the December 20, 2012 issue of BML Open confirms the USPSTF’s recognition that effective nutrition services are most often provided by RDs, not primary care providers: “only 44 percent of primary care physicians reported success in helping obese patients lose weight and that primary care physicians identified nutritionists and dietitians as the most qualified providers to care for obese patients.”

**RD-Provided Comprehensive Nutrition Services Are Cost-Effective**

RD-provided nutrition services are affordable, cost-effective, and are part of a comprehensive package of preventive and disease management services that would help to improve our nation’s health. Explicitly defining certain preventive and wellness services and chronic disease management in the EHB also offers the United States an unique opportunity to lower long-term health care costs by eliminating the often cited “free-rider” argument that a health insurer’s provision of preventive services are likely to inure to another insurer years later. By eliminating the free-rider argument and including comprehensive preventive services, overall health will be improved with fewer incidences of costly chronic disease management. In short, HHS can improve the risk pool for all plans and payers by ensuring all evidence-based efficacious preventive services are included in the EHB.

Including RD-provided MNT in a health plan is not only clinically effective, it is cost effective. As just one example, a study conducted at Massachusetts General Hospital

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14 See, USPSTF Evidence Review. Effectiveness of Primary Care–Relevant Treatments for Obesity in Adults. Accessed December 24, 2012 at http://www.uspreventiveservicestaskforce.org/uspstf11/obeseadult/obesers.htm (“[Most of the successful behavioral-based interventions in the United States were not highly applicable to primary care.”)
demonstrated a savings of $4.28 for each dollar spent on MNT.\textsuperscript{16} According to an imminently forthcoming Blue Cross Blue Shield study, “[h]ealth plans that have added these services to their benefits packages (up to unlimited visits report the additional cost has been 3 cents per member per month.”\textsuperscript{17} Additionally, according to Wolf, \textit{et al}, for every dollar an employer invests in the lifestyle modification program for employees with diabetes, the employer would see a return of $2.67 in productivity. MNT provided by RDs also impacts productivity; the study indicated the RD-led lifestyle intervention provided to patients with diabetes and obesity reduced the risk of having lost work days by 64.3\% and disability days by 87.2\%, compared with those receiving usual medical care.\textsuperscript{18} Nutrition interventions reduce and even eliminate the need for costly long-term medications and reduce hospitalizations. HHS and the Treasury and the Labor Departments (at page 41736 of volume 75 of the Federal Register) found that nutrition services for obesity alone reduce premiums by 0.05 to 0.1 percent. As such, they meet the criteria of good stewardship of resources.

\textbf{Benefits Related to Obesity}

The Academy is pleased that certain provisions of the ACA appear to protect patient access to and coverage of obesity treatment services. For example, individuals affected by obesity will now have access to covered obesity screening and referral to intensive, multi-component behavioral interventions, as these “preventive” services are recommended by the USPSTF with a B rating and are thus mandated under the ACA. Obesity is a complex, multifactorial chronic disease, which requires a multidisciplinary treatment approach. While HHS may be reluctant to explicitly mandate coverage of obesity treatment services as part of a state EHB-benchmark plan, we believe that, at a minimum, HHS should clarify whether management of obesity and metabolic disorders are chronic disease management services and are therefore covered services under the “Preventive and Wellness Services and Chronic Disease Management” category of the essential health benefits package.

Regrettably, many private health plans have misguidedly excluded coverage for obesity treatment services because of shortsighted cost savings efforts and a false assumption that these services are either not medically necessary or not in line with generally accepted standards of medical care. As a result, many Americans with obesity are effectively discriminated against because they are unable to receive the necessary care for their medical condition. The Academy supports the proposed rule’s prohibition of “benefit and network designs that discriminate on the basis of an individual’s medical condition,” and urges HHS to ensure proper inclusion of obesity treatment in EHB-benchmark plans in accordance with the proposed discrimination prohibition. The Academy seeks clarification that MNT and intensive behavioral counseling for management of obesity is included in the pediatric services EHB category. The Academy also reiterates that “weight loss services”

\textsuperscript{17} Personal Communication from Gwen Murphy to Marsha Schofield, dated August 16, 2012.
are not obesity treatment, and thus any exclusions in base-benchmark plans for “weight loss services” do not and should not indicate that coverage for management of the chronic disease of obesity is excluded.

The Academy believes that individuals affected by severe obesity should have access to bariatric surgery with comprehensive pre- and post-surgery nutrition evaluation and counseling to ensure the efficacy and cost-effectiveness of the bariatric surgery benefit over the long-term. In reviewing state benchmark plan selections, HHS should recognize that bariatric surgery is already widely covered by Medicare, TRICARE, 47 State Medicaid plans and 44 State employee plans. In addition, Mercer’s 2010 National Survey of Employer-Sponsored Health Plans show that bariatric surgery is covered by 40% of plans with fewer than 500 employees and is also that the fastest growth in coverage is in small employers (<500) which is growing at 8% annually. Allowing states to ignore a widely covered treatment avenue for this serious chronic disease would both disadvantage and discriminate against a significant portion of Americans who would clearly benefit from this medically necessary intervention.

Evidence-Based Medications
The Academy is concerned that the prescription drug benefit in the EHB in the proposed rule does not provide appropriate protections for people with chronic conditions like diabetes, HIV/AIDS, and obesity. While the requirement to cover the greater of 1 or the number of drugs in a benchmark plan’s category is an improvement over the requirements outlined in the pre-rule bulletin, the new regulation could still result in insufficient access to medications for people with diabetes, HIV/AIDS, obesity, and other chronic conditions. Specifically, we are concerned that focusing on a number of drugs covered, as opposed to ensuring a breadth of drugs are covered, could result in a selection of drugs that meets the minimum requirement yet still discriminates against potential enrollees. Furthermore, the requirements in the proposed rule only refer to coverage, not tiering or utilization management controls, which can have a significant impact on access to critical medications. The Academy requests that HHS require states to implement beneficiary protections consistent with Part D, where CMS considers the specific drugs, tiering and utilization management strategies employed in each formulary and identifies outliers from common benefit management practices for further evaluation.19

Finally, we recommend that a state supplement its EHB-benchmark plan to include new safe, effective, and evidence-based medications for treatment of obesity that have been approved by the FDA and are either available or will soon be available to the citizens of the state. These medications present exciting new options for medical therapy, particularly for those who do not respond to behavioral intervention or those patients who may not yet be ready for bariatric surgery. The weight loss accompanying these medications has been shown to prevent progression to diabetes in high risk patients, and to reduce the need for additional medications used to treat diabetes and hypertension.

The Academy appreciates the multiple opportunities for comment throughout the EHB development process. We recognize the complexity of defining EHB and offer our assistance and evidence analysis regarding implicated benefits to support HHS’s goal of regularly updating the EHB to reflect scientific advances. As one of the first professional groups to embrace evidence-based practice, the Academy created the world’s first evidence-analysis nutrition library and produces guides for condition-specific nutrition care that we hope you will look towards as you update the benefits package. 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,

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