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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Parts 405, 410, 411, 414, 417, 422, 460
RIN:0938-AS81

Medicare Program: Payment Policies under the Physician Fee Schedule; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release

The Board for Certification of Nutrition Specialists℠ (BCNS℠) appreciates the opportunity to submit comments in response to the above referenced proposed rule, CMS-2016-0116-0006 (July 15, 2016).

We focus our comments on section F. *Improving Payment Accuracy for Services: Diabetes Self-Management Training (DSMT)* and section J. *Proposed Expansion of the Diabetes Prevention Program (DPP) Model.*

The BCNS is the foremost certifying body for advanced nutrition professionals. Our Certified Nutrition Specialist® (CNS®) certificants earn an advanced degree in nutrition or clinical healthcare, complete a robust nutrition science curriculum, perform 1,000 hours of documented nutrition practice experience, and pass the rigorous, BCNS Certification Examination for Nutrition Specialists℠.

The CNS certification is fully accredited by the National Commission for Certifying Agencies, the preeminent, national accrediting organization for certifying programs, which is the same accreditation held by the Registered Dietitian® credential. The CNS certification is listed by the U.S. Department of Labor as an advanced nutrition credential in the definition of the "Dietitians and Nutritionists" profession in the Occupational Outlook Handbook of the Bureau of Labor and Statistics.[1]

BCNS alerts CMS to multiple barriers to access to DSMT as requested in F. *Improving Payment Accuracy for Services: Diabetes Self-Management Training (DSMT)* including:

- Outdated standards and private credentials that block qualified nutrition professionals (such as but not limited to Certified Nutrition Specialists) as potential providers, existing within? Medicare, the national standards and the existing NAO-approved credentials
- Regulation of one treatment approach to one disease as if it were a profession
- Accessibility to DSMT blocked by a restriction on providers requiring that they already be certified as Medicare providers
- Overly burdensome organizational requirements within the national standards to becoming a DSMT provider
- Lack of clarity on alternative educational and experiential qualifications for becoming a provider

Certified Nutrition Specialists Highly Skilled in Diabetes Care

The proposed rule outlines the intent and scope of DSMT:

> "DSMT services are intended to educate beneficiaries in the successful self-management of diabetes. DSMT includes, as applicable, instructions in self-monitoring

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> of blood glucose; education about diet and exercise; an insulin treatment plan developed specifically for the patient who is insulin-dependent; and motivation for patients to use the new skills for self-management (see § 410.144(a)(5)).”[2]

DSMT is an important benefit that has the potential to significantly alter the disease trajectory, quality of life and medical costs over a lifetime for those with diabetes. We applaud CMS's intent to increase utilization of this benefit and seek to make constructive suggestions for achieving that goal.

As evidence unequivocally points to controllable lifestyle factors in the prevention, management, and even reversal of diabetes and prediabetes, we suggest that any ruling seeking to increase access to DSMT should be structured in such a way as to maximize access by the public to those professionals who have met high standards in the provision of nutrition care, as the CNS has. Concomitantly, additional specialized training for qualified nutrition care professionals who want to provide DSMT should not be overly burdensome to obtain, either in time or financial costs.

With advanced health care degrees and training in the use of clinical nutrition to prevent and manage chronic disease including diabetes, CNSs are eminently qualified to provide medical nutrition therapy, nutrition counseling, support and education for those with diabetes and prediabetes. These services are a key component of the work of CNSs in both community and institutional settings. CNSs should be among the leaders in the provision of DSMT. However, many structural components of how the benefit is currently made available, prevent this from happening and prevent the DSMT provider network from growing. This in turn defeats the goal of increased utilization.

Proposed Medicare Provider Prerequisites Treat DSMT as a Profession Rather than a Discreet Approach to a Single Disease

The rule's proposed prerequisite that all DSMT providers be certified to provide other services under Medicare restricts, and will continue to restrict, access to and availability of DSMT delivered by qualified providers.

> Section 1861(qq) of the Act specifies that DMST services are furnished by a certified provider, defined as a physician or other individual or entity that also provides, in addition to DSMT, other items or services for which payment may be made under Medicare.[3]

DSMT is a discreet approach to one disease; it is not a profession unto itself. Because licensed professionals get additional specialized training for DSMT and also must be approved apart from Medicare to provide DSMT, we question the utility of layering over that the additional, pre-existing Medicare provider certification requirement. It is duplicative in light of the additional quality measures DSMT providers must meet. We recommend CMS consider removing the Section 1861 (qq) requirement, which we believe constrains the growth of the DSMT provider workforce contrary to the goal of the proposed rule.

We also point to section § 410.79 Medicare diabetes prevention program expanded model: Conditions of coverage of this proposed rule, in which a new category of suppliers of the Diabetes Prevention Program, MDPP Coaches, is being considered for those who: are not certified as Medicare providers; meet the CDC standard to provide DPP; and want to provide this specific program to beneficiaries. In this instance, CMS has proposed for consideration recognizing a new category of suppliers who meet the CDC guidelines for DPP instructor and who acquire an NPI number. We think a similar model used for DSMT suppliers would lead to a large expansion of available, qualified providers of the benefit.

Unwarranted Barriers to Entry in Current DSMT Provider Standards

> "We require that all those who furnish DSMT services be accredited as meeting quality standards by a CMS-approved national accreditation organization (NAO). In accordance with § 410.144 a CMS-approved NAO may accredit an individual, physician or entity to meet one of three sets of DSMT quality standards: CMS quality standards; the National Standards for Diabetes Self Management Education Programs (National Standards); or the standards of an NAO that represents individuals with diabetes that meet or exceed our quality standards."[4]

We would like to call attention to and outline several barriers to expansion of DSMT services that exist in the standards set by current CMS-approved national accrediting organizations, the national standards and by the CMS quality standards. Although we recognize that it is not the role of CMS to determine national standards, we want to respond to the request in this proposed rule to identify barriers to access of which CMS may not be aware and suggest possible ways to address these barriers.

I. ***All* qualified nutrition and dietetics professionals with training and experience pertinent to DSMT, should be deemed eligible to be responsible for designing and planning DSMT rather than limiting the category to holders of one, private association credential in the broader nutrition profession.** Standard number five of the national standards requires that:

> "At least one of the instructors responsible for designing and planning DSME and DSMS will be a registered nurse, *registered dietitian* regulated, or pharmacist with training and experience pertinent to DSME, or another professional with certification in diabetes care and education, such as a CDE or BC-ADM".[5] This proposed change would be consistent with CMS' 2014 ruling "Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II" in § 482.28 Food and Dietetic Services[6] wherein CMS noted that patients are served by a more flexible approach to the inclusion of qualified nutrition professionals rather than narrowing to holders of specific, private association credential. We hope that CMS would take a similar approach to providers of DSMT to accomplish the goal of expanded access to this important benefit.

II. **Remove unwarranted barriers to credentialing of all qualified nutrition professionals**
Although standard five does have a provision for other professionals with certification in diabetes care and education such as the CDE or the BC-ADM, we call attention to the fact that neither association issuing those credentials identifies licensed or certified nutrition professionals who are not registered dietitians, as automatically qualifying to sit for their respective credentialing exams, as is done for nurses, dietitians, pharmacists, and other health care professionals. The BC-ADM credential has *profession-based* requirements for all professions except nutrition and dietetics for which it has a *single, private association credential* (the RD®) requirement. All other named professions require licensure in the profession, but there is no equivalent option identified for either privately credentialed, or state licensed nutritionists who are not dietitians to become a BC-ADM. Thus far, BCNS and AADE have not reached a solution to this omission in almost three years of discussing the problem. The CDE credential provides a "unique qualifier pathway," a more burdensome solution than required of other health professions. These barriers to credentialing make it difficult for highly qualified nutrition professionals with education and experience in diabetes care to become DSMT providers.

III. **Define a standard for "education and experience in diabetes management"**
We note that in the document "Clarification of National Standards Permitting Qualified RDs,

RNs, or Pharmacists to Individually Furnish Diabetes Self-Management Training Services"[7] CMS states "The National Standards continue to call for all of the instructor(s) on the diabetes team to be certified as diabetes educator(s) *or have recent educational and experiential preparation in education and diabetes management"* (emphasis added). We have looked but not found within the national standards or elsewhere an articulated, alternative-qualifying method thru education and experience. Professionals of different training backgrounds will have varying levels of education and experience in diabetes education and management. In the interest of increasing the availability of the DSMT benefit, we recommend further elucidation of this method of qualifying.

IV. **Maintain clear and separate provider standards for DPP and DSMT**

The national standards appear to be moving toward merging diabetes self-management education and prediabetes prevention:

> "Although the term "diabetes" is used predominantly, the Standards should also be understood to apply to the education and support of people with prediabetes. Currently, there are significant barriers to the provision of education and support to those with prediabetes. And yet, the strategies for supporting successful behavior change and the healthy behaviors recommended for people with prediabetes are largely identical to those for individuals with diabetes. As barriers to care are overcome, providers of DSME and diabetes self-management support (DSMS), given their training and experience, are particularly well equipped to assist individuals with prediabetes in developing and maintaining behaviors that can prevent or delay the onset of diabetes."[8]

As prediabetes and diabetes fall along a continuum, this on the one hand makes sense to consider both within the national standards. On the other hand, we caution against any future approach to diabetes prevention services that moves toward applying the current accreditation standards for DSMT in determining which providers will be qualified to provide support and education in healthy behaviors and lifestyle change to people who do not yet have diabetes. Much of the DSMT curriculum is specific to medications, use of devices, etc., which is not part of diabetes prevention, and requires a different set of educational and experiential tools for the provider**.** We heartily agree that the behavior change and healthy behavior recommendations for prediabetes are largely, though not completely, identical to those required for addressing diabetes. However, we stress that the diabetes prevention program, also being recommended for expansion in this proposed rule *because* of its overwhelming success, has been successfully delivered in its current format with significantly less burdensome and less costly restrictions on providers.

We strongly believe it would be contrary to the goals of slowing the diabetes epidemic to apply the existing DSMT provider standards to diabetes prevention providers. One of the successes of the DPP is its ability to be delivered in a variety of non-medical settings by a broad range of trained instructors (which could be, but is not limited to credentialed health care professionals) providing both broad outreach and cost effectiveness. To require more training than has been demonstrated to be effective in slowing the rate of onset of diabetes wastes resources of Medicare and of the providers.

V. **Update the "rural area" provider standards in CMS quality standards**

CMS quality standards as defined in § 410.144 pose another barrier to access to the DSMT benefit.

> "(ii) In a rural area, an individual who is qualified as a registered dietitian and as a CDE that is currently certified by an organization approved by CMS (or until February 27, 2004 an individual who is qualified as a registered dietitian and as a

registered nurse) may furnish training and is deemed to meet the multidisciplinary team requirement in paragraph (a)(4)(i) of this section."[9]

As in item I above, the limitation of this clause to holders of only one private credential within a broader profession is an outdated limitation we urge CMS to update to expand potential DSMT providers in rural, underserved areas. Changing this qualification to a licensed dietetics or nutrition professional with the additional qualification of meeting a diabetes educator standard approved by CMS, would remove this current limitation. Identifying the profession, rather than a single credential, would also create a flexible framework for drawing DSMT providers from an expanding nutrition profession.

VI. Reevaluate organizational structure requirements in the national standards

While once DSMT had to be delivered within organizations by teams, solo providers can now deliver the benefit. However, the burden of establishing and defining an extensive organizational structure to meet the national standards, perhaps appropriate to institutions, serves as a deterrent for a solo practitioner (such as a private practice nutritionist, social worker or psychologist). The standards themselves point to insufficient evidence on the benefit of organizational structure on effectiveness of DSMT.

"In the course of its work on the Standards, the Task Force identified areas in which there is currently an insufficient amount of research. In particular, there are three areas in which the Task Force recommends additional research:
1. What is the influence of organizational structure on the effectiveness of the provision of DSME and DSMS?"[10]

These extensive requirements serve as a deterrent to many qualified providers. Many could and would supplement their existing training to provide DSMT were it not for the amount of time, money and paperwork, in addition to training, to create and document an unproven element of effectiveness. We suggest a more streamlined requirement highlighting goals and methods of documenting outcomes for this standard would attract more DSMT providers.

Removing Regulatory Impediments to Expanded DSMT Access

In the proposed rule, CMS notes that the DSMT benefit is severely underutilized:

"An article titled "Use of Medicare'. Diabetes Self-Management Training Benefit" was published in the *Health* Education Behavior on January 23, 2015. The article noted that only 5 percent of Medicare beneficiaries with newly diagnosed diabetes used DSMT services. The article recommended that future research identify barriers to DSMT access."[11]

Current requirements to become a DSMT provider, after one has already obtained a primary health care degree and license or certification, are costly and time consuming. These requirements impose significant secondary, ongoing, costs and requirements in addition to the requirements and costs of the provider's primary license.[12]

Effectively requiring of all professionals what amounts to a second licensure to provide a single service for a single disease does not make sense when chronic disease is rampant in our nation and DSMT is dramatically underutilized. Continuing education for licensed professionals has always served the purpose of acquiring additional needed skills relevant to their professions. We suggest a similar approach be utilized here, modified to specify the diabetes-related competencies that need to be acquired and demonstrated in a less burdensome way than is presently required or proposed in this rule.

The BCNS urges CMS to consider a less restrictive and a more cohesive process for qualifying DSMT providers. Excluding all highly qualified nutritionists who are not registered dietitians, however unintentional, is problematic and counterproductive. As experts in providing dietary advice and medical nutrition therapy for diabetes, nutrition professionals such as the Certified Nutrition Specialist, as well as all professions whose work touches on diabetes, should be encouraged by a sensible regulatory approach to provide the DSMT benefit rather than turned away by multiple barriers and hurdles.

Finally, because of the centrality of diet, exercise and obesity to the onset and trajectory of diabetes, nutrition and lifestyle strategies should be at the core of any national strategy for curbing this epidemic and cutting the cost of care. Though we recognize the importance of medical management in diabetes and in the DSMT skill set, medical management of diabetes over a lifetime is far more costly than an approach that has the evidence-based potential to reduce or eliminate the need for medication. We urge CMS to call for data collection by the physician and nutrition professional communities that are successfully addressing and reversing diabetes through lifestyle intervention as an important step to promoting an even stronger lifestyle approach to DSMT and diabetes.

Diabetes Prevention Program: A Model for Cost-Effective Lifestyle Intervention in Chronic Disease

The BCNS stands in support of the addition of the proposed Medicare Diabetes Prevention Program which we believe has the potential to:

- Significantly reduce new cases of diabetes and diabetes-related comorbidities
- Build and expand healthy community engagement efforts
- Utilize cost effective human resources to achieve results and cost savings
- Serve as a model for future lifestyle approaches to chronic diseases

The original research conducted in 2002 on the DPP model showed very favorable results for the program's effectiveness in reversing the progression to diabetes:

> "The lifestyle intervention reduced the incidence by 58 percent (95 percent confidence interval, 48 to 66 percent) and metformin by 31 percent (95 percent confidence interval, 17 to 43 percent), as compared with placebo; the lifestyle intervention was significantly more effective than metformin. To prevent one case of diabetes during a period of three years, 6.9 persons would have to participate in the lifestyle-intervention program, and 13.9 would have to receive metformin."[13]

More recent data from the Health Care Innovation Awards evaluation project, testing specifically within the Medicare population through the "Y" organization, shows similarly positive results.

The ability of the DPP program to be effectively delivered by trained providers, including lay community members, community health workers, health coaches and health professionals translates to an intervention that is less costly, more widely accessible and more culturally sensitive and appropriate.

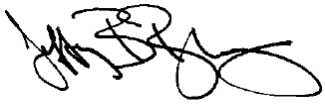
Creating a new supplier class, MDPP Coaches and testing remote access programs, we think are both innovative approaches to expanding distribution of the MDPP by developing a network of coaches with ties to those communities. In addition to increasing access, this approach has the potential to address the challenge (noted in the "Evaluation of the Health Care Innovation Awards: Community

Resource Planning, Prevention, and Monitoring" 2016 Annual Report) faced by the "Y" of recruiting more Medicare aged participants. Creating a supplier class of MDPP Coaches, tied either into other organizations or directly into Medicare, simply builds a more expansive network that can reach greater numbers of prospective participants.

Certified Nutrition Specialists are on the forefront of providing evidence-based medical nutrition therapy to those with chronic diseases. On a daily basis, CNSs employ nutrition tools to address chronic disease and other health issues. We are heartened to see CMS move toward implementing a nutrition and lifestyle approach to slowing the diabetes epidemic as a Medicare benefit. We think the future of our nation's health will be brighter with increased innovation utilizing evidenced-based nutrition approaches to disease.

We appreciate the opportunity to provide input to CMS on the utilization of both the DSMT and the DPP programs as tools in addressing the nation's critical diabetes epidemic.

Sincerely,



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[1] http://www.bls.gov/ooh/healthcare/dietitians-and-nutritionists.htm#tab-4
[2] Federal Register / Vol. 61. No. 136/ Friday. July 15. 2016/Proposed Rules p. 46215
[3] op. cit. see endnote 2, p 46215
[4] op. cit. see endnote 2 p. 46215-6
[5] op. cit. see endnote 4 p s146
[6] Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II p 46-48
[7] Clarification of National Standards Permitting Qualified RDs, RNs, or Pharmacists to Individually Furnish Diabetes Self-Management Training Services CMS PERL 201102-48
[8] op, cit see endnote 9 p. 1-2
[9] Diabetes Self Management Training, CFR-2008-title42-vol2-sec410-144, Program Staff (3)(C)(ii)
[10] National Standards for Diabetes Self-Management Education and Support Diabetes Care Volume 37, Supplement 1, January 2014 p s145
[11] op. cit. see endnote 2 p. 46216
[12] See Appendix A for Chart of DSMT Credential Requirements and Costs
[13] Diabetes Prevention Program Research Group. *Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin.* N Engl J of Med:2002.
http://www.nejm.org/doi/full/10.1056/NEJMoa012512#t=article

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Appendix A

Chart of DSMT Credential Requirements and Costs

Credential	Initial Exam Cost	Materials Cost	Practice Requirement (Verified)	Renewal Interval and Cost	Renewal CE Requirement	Renewal Practice Requirement (Verified)
BC-ADM	$600-$900 (lower fee requires paid membership)	Varies, but can include books, CE classes, mentored study groups and supervision	500 hours post-advanced professional degree (no recognition of non-RD nutrition professionals)	5 years/ $500-$800	Accepts CE hours of the licensed profession	1,000 hours
NCBDE	$350	Cost of mandatory 30 hours of diabetes CEs, can also include books, mentored study groups and supervision	1,000 hours for recognized professions/RDs; 2,000 hours for MS and above non-RD nutritionists applying through "Unique Qualifier Pathway"	5 years/ $250	75 hours in Diabetes specific CEs	1,000 hours (or re-exam plus 75 CE hours)

Sources:

http://castleworldwide.com/aade/AppSystem/6/Public/Resource/AADE_Candidate_Handbook.pdf

http://www.ncbde.org/assets/1/7/Handbook_Current.pdf