DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3205–FN]

Medicare Program; Application by the American Association of Diabetes Educators (AADE) for Recognition as a National Accreditation Organization (NAO) for Accrediting Entities To Furnish Outpatient Diabetes Self-Management Training (DSMT)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces the approval of an application from the American Association of Diabetes Educators (AADE) for recognition as a National Accreditation Organization (NAO) for accrediting entities that wish to furnish outpatient Diabetes Self-Management Training (DSMT) to Medicare beneficiaries. Approval is for a period of 3 years.

DATES: *Effective Date:* This final notice is effective on March 30, 2009.

FOR FURTHER INFORMATION CONTACT: Joan A. Moliki, (410) 786–5526. Eva Fung, (410) 786–7539.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive outpatient Diabetes Self-Management Training (DSMT) when ordered by a physician (or qualified non-physician practitioner) provided certain requirements are met, as set out at 42 CFR 410.141. Our regulations at 42 CFR 410.141(e)(3) require that a DSMT program be accredited by a National Accreditation Organization (NAO) so that it can be determined if the program meets the requirements set out at § 410.144 when providing DSMT services for which Medicare payment is made.

Under section 1865(a)(1) of the Social Security Act (the Act), the Secretary must find that accreditation by a NAO demonstrates that the standards and requirements specified by the Secretary with regard to a provider are met in order for the NAO to qualify for deeming authority. We may evaluate and recognize a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish training. The regulations pertaining to requests by a national organization to be recognized as a NAO for DSMT are set out at 42 CFR 410.142. Entities applying for NAO status must demonstrate that they apply one of the sets of quality standards to the DSMT programs that they accredit as set out at 42 CFR 410.144. Our review and evaluation of the applicant organization's ability to maintain the standards and to apply them to accredited entities must provide assurance that DSMT services are able to be furnished consistent with federal requirements. Section 1865(a)(2) of the Act further requires that we consider, among other factors, with respect to a national accrediting body the following—

- Organization's requirements for accreditation,
- Its survey procedures,
- Its ability to provide adequate resources for conducting required surveys,
- Its ability to supply information for use in enforcement activities,
- Its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and
- Its ability to provide us with necessary data for validation.

Section 1865(a)(3)(A) of the Act requires that we publish a notice identifying the national accreditation body making the request within 30 days of receipt of a completed application. The notice must describe the nature of the request and provide at least a 30-day public comment period. We have 210 days from receipt of the request to publish a finding of approval or denial of the application. If, after our review and evaluation, we determine an applicant organization meets all necessary requirements, any entity accredited by the organization will be ''deemed'' to meet the Medicare requirements.

II. Provisions of the Proposed Notice

On October 24, 2008, we published a proposed notice in the **Federal Register** (73 FR 63483) to notify the public of American Association of Diabetes Educators' (AADE) request for approval of its accreditation program to deem entities furnishing DSMT services.

Conditions for Coverage and Requirements for Outpatient DSMT

As noted above, the regulations specifying the Medicare conditions for coverage for outpatient DSMT are located in 42 CFR parts 410, subpart H. These conditions implement section 1861(qq) of the Act, which provides for Medicare Part B coverage of outpatient DSMT as specified by the Secretary.

Under section 1865(a)(2) of the Act and our regulations at § 410.142 (CMS Process for approving NAOs) and § 410.143 (Requirements for approved accreditation organizations), we review and evaluate the application of national organizations to be recognized as NAOs for DSMT. A national organization seeking recognition as a NAO must demonstrate that it applies one of three sets of quality standards to DSMT programs: the Medicare quality standards found at 42 CFR § 410.144(a); the National Standards for Diabetes Self-Management Education Programs (NSDSMEP), pursuant to § 410.144(b); or the standards of a national organization representing individuals with diabetes that meet or exceed Medicare standards.

We may conduct an on-site inspection of a NAO's office and operations to verify information in the organization's application and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing documentation of meetings concerning the accreditation process, evaluating accreditation results or the accreditation status decisionmaking process and interviewing the organization's staff.

III. Analysis of and Responses to Public Comments on the Proposed Notice

We received 16 items of correspondence containing 9 different comments. A summary of these comments and our responses are set forth below.

Comment: A few commenters supported the approval of the AADE to deem DSMT programs. The commenters stated that the approval of AADE would empower the organization to train healthcare professionals to educate an ailing population on diabetes self-management. They further stated that AADE's proposed quality standards would increase access to community-based DSMT programs, enable programs to conduct training in real-life settings, enhance behavior changes, and lead to improved clinical outcomes and patient satisfaction.

Response: We thank the commenters for their comments. The goal of the DSMT program is to provide beneficiaries with tools to better manage their diabetes and to achieve good clinical and behavioral outcomes.

Comment: One commenter urged CMS to ensure proper alignment of the AADE quality standards with CMS standards in order to assure quality DSMT education is delivered to beneficiaries. Another commenter suggested CMS use the NSDSMEP to evaluate AADE standards.

Response: Instead of using its own set of quality standards to deem DSMT entities as proposed in its initial application, AADE has elected to adopt and abide by the NSDSMEP standards. We performed an extensive review of the AADE accrediting policies and procedures, and assessed its proposed implementation strategies for the NSDSMEP. We concluded that they are consistent with the NSDSMEP and meet our requirements.

Comment: One commenter stated that the NSDSMEP requires the appointment of an advisory committee to promote quality and meet patient and community needs. The commenter noted that AADE's proposed policies did not address the requirement for such oversight or input. The commenter believed that AADE policies were therefore less stringent than the CMS quality improvement standard, which requires an entity to either have an agreement with a Quality Improvement Organization (QIO) to participate in a specified quality improvement project or demonstrate a level of achievement through a comparable project of its own design.

Response: Subsequent to its decision to adopt the NSDSMEP, AADE revised its policies to include a patient-centered and consumer-focused advisory group to provide input for planning, developing, evaluating, and collaborating DSMT efforts to better serve the community. We conducted a thorough review of AADE's revised policies and determined that they meet applicable standards.

Comment: Some commenters strongly objected to AADE's proposed standard which would have allowed non-professionals to be instructors on the DSMT team. They were concerned that the quality and accuracy of the DSMT would be significantly compromised. The commenters believed that the non-professional instructors could not stay current on the rapidly evolving treatment strategies due to their limited education and credentials. One commenter cited studies to demonstrate the lack of evidence to support the effectiveness of lay health workers in primary and community health care.

Response: We fully agree with the commenters that DSMT instructors should have qualified credentials in order to provide quality DSMT to Medicare beneficiaries. With AADE's adoption of the NSDSMEP, non-professionals will not be permitted to be a part of an accredited DSMT program's instructional team in an instructional capacity. Instead, AADE will limit their responsibilities to non-instructional and non-technical roles, in which they will perform a variety of support functions to enhance patients' self-management skills. Additionally, AADE requires evidence, as appropriate, of current licenses, registration and/or certification of instructors.

Comment: Some commenters raised concerns that AADE did not clearly define ''the use of non-clinical staff (such as, community health workers) to deliver diabetes education, with supervision by professional staff.'' The commenters further noted that AADE did not address the audit process for the training or on-going education of these non-professional instructors. One commenter stated that the non-professional staff should not be authorized to provide DSMT independently and that their work would need to be actively supervised by appropriate credentialed professional staff.

Response: As stated previously, AADE accreditation standards no longer permit accredited DSMT programs to include non-professionals as instructors on the DSMT team. AADE will require that the responsibilities of community health workers on the DSMT team be non-instructional and non-technical. They will receive training and be directly supervised by diabetes educators in the program. We believe that there are merits in using non-professional staff such as community health workers in collaborative programs such as DSMT. With training and supervision as required, non-professional staff can provide social support to beneficiaries, facilitate access to services and enhance cultural competency of service delivery.

Comment: One commenter strongly supported the requirement for a certified diabetes educator (CDE) on the instructional team.

Response: With the adoption of the NSDSMEP, AADE-accredited DSMT entities may include instructors who are certified diabetes educator(s).

Comment: One commenter stated that a physician-led team approach should be used to deliver cost-effective diabetes education.

Response: The leadership role of the physician has not changed. Under § 410.141, Outpatient DSMT, the physician or qualified non-physician practitioner treating the beneficiary's diabetes is charged with evaluating the beneficiary's need for training. He or she sets out the comprehensive plan of care; provides guidance on plan content, the number of sessions, frequency, and duration of services; and provides follow-up as necessary. Furthermore, the DSMT entity is expected to periodically update the referring physician about the beneficiary's outcomes, goals, and educational status.

Comment: One commenter stated that the AADE's proposed standards did not clarify how the accredited DSMT program would be able to meet beneficiaries' needs that were outside the solo instructor's scope of practice and expertise. In addition, the commenter stated that it was unclear how collaboration and linkages with other external health care providers of different disciplines would occur with only a solo program instructor.

Response: AADE now requires programs that have solo instructors to establish a mechanism for ensuring that participant needs are met if these needs are outside the instructor's scope of practice and expertise.

Comment: One commenter expressed concern that AADE's proposed standard #6 would have allowed DSMT to be delivered through telecommunication media, while the 2009 Medicare Physician Fee Schedule Final Rule specifically disallows payment for telehealth provision of services as a substitute for face-to-face DSMT service.

Response: We agree with the commenter that the delivery of DSMT through telecommunication services does not meet the intent of our DSMT standards, which promote interactive, face-to-face and collaborative learning. To comply with Medicare policy on payment for telehealth services, AADE has removed the language on the permissibility of providing DSMT via telecommunication services from its Interpretive Guidance and notes in its policy that we do not reimburse for DSMT provided via telehealth.

Comment: One commenter recommended that AADE be more explicit in describing the training program for volunteer auditors.

Response: AADE revised its policies to strengthen the training program for volunteer auditors to ensure consistent application of the standards to all DSMT programs.

Comment: One commenter requested that AADE clarify the percentage of programs it audits in the initial application phase as well as in the accreditation period.

Response: AADE's policy on random on-site audit specifies 5 percent of applicants for initial accreditation, 10 percent of accredited programs during an accreditation cycle and 10 percent of applicants applying for re-accreditation.

Comment: One commenter requested clarification of the AADE requirement for continuous quality improvement activities for accredited programs.

Response: For continuous quality improvement activities, AADE has

specific policies and procedures in place that require accredited programs to have a systematic process for implementing a continuous quality improvement process and plan, that is, programs are required to develop projects of their own design, and to specify the outcome measures they are currently tracking, providing a rationale for selecting the outcome measures. Furthermore, AADE also requires an accredited program to undertake quality improvement activities annually.

Comment: One commenter stated that AADE's proposed re-accreditation methodology that would perform random checks on providers' professional licenses, certificates and continuing education, would be inadequate, since the staffing turnover in DSMT programs is high. Random credential validation could pose a potential quality assurance problem.

Response: We agree with the commenter that an accrediting organization should comprehensively validate professional licenses, certificates and continuing education in the re-accreditation phases to ensure DSMT programs provide quality care by qualified staff. AADE's reaccreditation methodology now requires programs to notify the AADE of any change in staff status, and to maintain documentation of current verification of professional licenses, certificates and continuing education for inspection during the re-accreditation process.

Comment: One commenter recommended that AADE adopt NSDSMEP standard #10, requiring the DSMT entity to measure the effectiveness of the education process and determine opportunities for improvement using a written continuous quality improvement plan that describes and documents a systematic review of the entity's process and outcome data.

Response: As stated earlier, AADE is adopting the NSDSMEP in its entirety, including standard #10.

Comment: A commenter expressed concerns that AADE standards would require its accredited programs to use the AADE7™ self-care behaviors and continuum of outcomes framework. This could create a potential conflict of interest if AADE-approved entities were required to purchase the AADE7™ framework as a condition of accreditation.

Response: We do not believe there is a conflict of interest if a prospective program makes the business decision to be accredited by the AADE and purchase the AADE7™ to enhance its data collection and quality improvement practices. Also, AADE allows its accredited programs the option to use other data collection tools. DSMT programs also have the option of seeking accreditation by either of the other NAOs for DSMT: the American Diabetes Association or the Indian Health Service (accrediting American Indian and Alaska Native programs).

Comment: One commenter suggested that in addition to granting deeming authority to NAOs, CMS should expand outreach efforts to increase access to DSMT programs by educating beneficiaries, physicians, and qualified non-physician practitioners (for example, nurse practitioners, physician assistants) to enhance their understanding of the DSMT referral process.

Response: This is beyond the scope of this final notice. However, educating more professionals about how to care for persons with diabetes, and educating more persons with diabetes about self-care is an area that we consider to be beneficial. Currently, there are a number of studies being conducted by our Quality Improvement Organizations. We expect to build on the lessons from these studies to further reduce disparities between health care received by minority populations and to be able to measure improvements as evidenced by these studies. It is anticipated that the studies will provide an opportunity to learn the most appropriate treatment modalities for a variety of serious health concerns, including diabetes, that are prevalent in our society.

IV. Provisions of the Final Notice

AADE's application to become a NAO for purposes of DSMT as authorized under Section 1861 (qq) of the Act is approved for a period of three (3) years and becomes effective 30 days after publication of this final notice. This approval is subject to renewal subsequent to the receipt of an application from the AADE and subject to review, evaluation and approval of its program.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 6, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9–3287 Filed 2–26–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4142–PN]

Medicare Program; Application of the Utilization Review Accreditation Commission (URAC) for Deeming Authority for Medicare Prescription Drug Plan (PDP) Sponsors

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice announces the application of the Utilization Review Accreditation Commission (URAC) for deeming authority as a national accreditation organization for prescription drug plan sponsors participating in the Voluntary Medicare Prescription Drug Benefit Program. This announcement describes the criteria to be used in evaluating the application and provides information for submitting comments during a 30 day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 30, 2009.

ADDRESSES: In commenting, please refer to file code CMS–4142–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment of Submission'' and enter the file code to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4142–PN, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.