


**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR**

**ACTION REFERRAL**

TO <i>Myers/Hamilton</i>	DATE <i>8/14/09</i>
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DIRECTOR'S USE ONLY		ACTION REQUESTED	
1. LOG NUMBER  <i>101083</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____	<input type="checkbox"/> Prepare reply for appropriate signature DATE DUE _____	<input type="checkbox"/> FOIA DATE DUE _____
2. DATE SIGNED BY DIRECTOR  	<input checked="" type="checkbox"/> Necessary Action		

APPROVALS <small>(Only when prepared for director's signature)</small>	APPROVE	* DISAPPROVE <small>(Note reason for disapproval and return to preparer.)</small>	COMMENT
1.			
2.			
3.			
4.			



American Association  
of Diabetes Educators

200 West Madison Street, Suite 800, Chicago, Illinois 60606

800.338.3633

Fax 312.424.2427

[www.diabeteseducator.org](http://www.diabeteseducator.org)

August 3, 2009

RECEIVED

Ms. Emma Forkner, Director  
Department of Health & Human Services

AUG 06 2009

P.O. Box 8206  
1801 Main Street  
Columbia, SC 29201-8206

Department of Health & Human Services  
OFFICE OF THE DIRECTOR

Dear Ms. Forkner,

I am writing to inform you that the American Association of Diabetes Educators (AADE) is now approved by CMS to accredit Diabetes Self-Management Education/Training Programs. These programs should be eligible for coverage and reimbursement, exactly the same as those accredited by others (ADA and HIS). Medicaid offices will need to update their policies to reflect this fact.

DSMT programs that are accredited by AADE are eligible for reimbursement from CMS. The February 27, 2009, Federal Register <http://edocket.access.gpo.gov/2009/pdf/E9-3287.pdf> ) announced the approval of AADE's application for recognition as a National Accreditation Organization (NAO).

AADE's Accreditation Program ensures the delivery of appropriate DSMT content to encourage behavior change and improve the health of people with diabetes. In addition, these accredited programs have provided evidence that they meet or exceed the National Standards for Diabetes Self-Management Education.

Some state Medicaid programs already cover and reimburse for diabetes education that is provided through programs that have been accredited by recognized groups (e.g., the American Diabetes Association (ADA) or Indian Health Service (HIS)). Therefore AADE's Accredited Programs that provide diabetes education should also be eligible for reimbursement, the same as others. We are encouraging programs to forward a copy of their AADE Certificate of Accreditation for your records with their bills, just as they do for Medicare.

You can review AADE's DSME/T accreditation website for additional information <http://www.diabeteseducator.org/accreditation>, and contact our Diabetes Education Accreditation staff at 800-338-3633 or [DEAP@aadenet.org](mailto:DEAP@aadenet.org) to answer any questions. Please share this information with staff in your contracting department and other areas involved in coverage and reimbursement.

I appreciate your consideration in this effort to improve the health outcomes of all people with diabetes.

Sincerely,

Lana Vukovljak  
Chief Executive Office

\* please send to felicity  
for consideration

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

ICMS-3205-FNI

#### 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 on-site 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.

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-accredited 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 (gg) 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]  
BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

ICMS-4142-PN1

### 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.