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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3316-PN]

Medicare and Medicaid Programs; Application by the American Diabetes Association for Continued Deeming Authority for Diabetes Self-Management Training

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

ACTION: Proposed notice.

SUMMARY: This proposed notice announces the receipt of an application from the American Diabetes Association for continued recognition as a national accreditation program for accrediting entities that wish to furnish outpatient diabetes self-management training to Medicare beneficiaries.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: In commenting, refer to file code CMS-3316-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 this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address **ONLY**:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3316-PN,
P.O. Box 8010,
Baltimore, MD 21244-8010.

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

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3316-PN,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written ONLY to the following addresses:

a. For delivery in Washington, DC--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Kristin Shifflett, (410) 786- 4133.

Jacqueline Leach, (410) 786-4282.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive outpatient Diabetes Self-Management Training (DSMT) when ordered by the physician (or qualified non-physician practitioner) treating the beneficiary's diabetes, provided certain requirements are met. Pursuant to our regulations at 42 CFR 410.141(e)(3), we use national accrediting organizations to assess whether provider entities meet Medicare requirements when providing services for which Medicare payment is made. If a provider entity is accredited by an approved accrediting organization, it is "deemed" to meet applicable Medicare requirements.

Under section 1865(a)(1)(B) of the Social Security Act (the Act), a national accrediting organization must have an agreement in effect with the Secretary of the Department of Health

and Human Services (the Secretary) and meet the standards and requirements specified by the Secretary in 42 CFR part 410, subpart H, to qualify for deeming authority. The regulations pertaining to application procedures for the national accreditation organizations for DSMT are specified at § 410.142 (CMS process for approving national accreditation organizations).

A national accreditation organization applying for deeming authority must provide us with reasonable assurance that the accrediting organization requires accredited entities to meet requirements that are at least as stringent as our requirements.

We may approve and recognize a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish training. The accreditation organization, after being approved and recognized by us, may accredit an entity to meet one of the sets of quality standards in § 410.144 (Quality standards for deemed entities).

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act further requires that we review the applying accreditation organization's requirements for accreditation, as follows:

- Survey procedures;
- Ability to provide adequate resources for conducting required surveys;
- Ability to supply information for use in enforcement activities;
- Monitoring procedures for providers found out of compliance with the conditions or requirements; and
- Ability to provide us with necessary data for validation.

We then examine the national accreditation organization's accreditation requirements to determine if they meet or exceed the Medicare conditions as we would have applied them.

Section 1865(a)(3)(A) of the Act requires that we publish a notice identifying the national accreditation organization that is making the request for approval or renewal within 60 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 CMS recognizes an accreditation organization in this manner, any entity accredited by the national accreditation organization's program for that service will be "deemed" to meet the Medicare conditions for coverage.

III. Evaluation of Deeming Authority Request

The purpose of this notice is to notify the public of the American Diabetes Association (ADA) request for the Secretary's approval of its accreditation program for outpatient DSMT services. The ADA submitted all the necessary materials to enable us to make a determination concerning its request for re-approval as a deeming organization for DSMTs. ADA was initially accredited on October 27, 2009 for a period of 6 years. This application was determined to be complete on March 13, 2015. This notice also solicits public comments on the ability of the ADA to continue to develop standards that meet or exceed the Medicare conditions for coverage, and apply them to entities furnishing outpatient services.

The regulations specifying the Medicare conditions for coverage for outpatient diabetes self-management training services 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 services specified by the Secretary.

Under section 1865(a)(2) of the Act and our regulations at § 410.142 (CMS process for approving accreditation organizations) and §410.143 (Requirements for approved accreditation

organizations), we review and evaluate a national accreditation organization based on (but not necessarily limited to) the criteria set forth in § 410.142(b).

We may conduct on-site inspections of a national accreditation organization's operations and office 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 decision making process, and interviewing the organization's staff.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document. Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a notice in the Federal Register announcing the result of our evaluation.

Dated: April 21, 2015

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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