

#### D. Speaker Declaration

On the day of the meeting, before the end of the meeting, all primary speakers and 5-minute speakers must provide a brief written summary of their comments and conclusions to the HCPCS Public Meeting Coordinator.

Each primary speaker and 5-minute speaker must declare in their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturers or competitors of any items being discussed; this includes any payment, salary, remuneration, or benefit provided to that speaker by the manufacturer or the manufacturer's representatives.

#### E. Written Comments From Meeting Attendees

Written comments will be accepted from the general public and meeting registrants anytime up to the date of the public meeting at which a request is discussed. Comments must be sent to the address listed in the **ADDRESSES** section of this notice.

Meeting attendees may also submit their written comments at the meeting. Due to the close timing of the public meetings, subsequent workgroup reconsiderations, and final decisions, we are able to consider only those comments received in writing by the close of the public meeting at which the request is discussed.

#### IV. Security, Building, and Parking Guidelines

The meetings are held within the CMS Complex which is not open to the general public. Visitors to the complex are required to show a valid U.S. Government issued photo identification, preferably a driver's license, at the time of entry. Participants will also be subject to a vehicular search before access to the complex is granted. Participants not in possession of a valid identification or who are in possession of prohibited items will be denied access to the complex. Prohibited items on Federal property include but are not limited to, alcoholic beverages, illegal narcotics, explosives, firearms or other dangerous weapons (including pocket knives), dogs or other animals except service animals. Once cleared for entry to the complex participants will be directed to parking by a security officer.

In order to ensure expedited entry into the building it is recommended that participants have their ID and a copy of their written meeting registration confirmation readily available and that they do not bring laptops or large/bulky items into the building. Participants are

reminded that photography on the CMS complex is prohibited. CMS has also been declared a tobacco free campus and violators are subject to legal action. In planning arrival time, we recommend allowing additional time to clear security. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes before the convening of the meeting each day.

Guest access to the complex is limited to the meeting area, the main lobby, and the cafeteria. If a visitor is found outside of those areas without proper escort they may be escorted out of the facility. Also be mindful that there will be an opportunity for everyone to speak and we request that everyone waits for the appropriate time to present their product or opinions. Disruptive behavior will not be tolerated and may result in removal from the meetings and escort from the complex. No visitor is allowed to attach USB cables, thumb drives or any other equipment to any CMS information technology (IT) system or hardware for any purpose at anytime. Additionally, CMS staff is prohibited from taking such actions on behalf of a visitor or utilizing any removable media provided by a visitor.

We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a presentation. Special arrangements and approvals are required at least 2 weeks prior to each public meeting in order to bring pieces of equipment or medical devices. These arrangements need to be made with the public meeting coordinator. It is possible that certain requests made in advance of the public meeting could be denied because of unique safety, security or handling issues related to the equipment. A minimum of 2 weeks is required for approvals and security procedures.

Any request not submitted at least 2 weeks in advance of the public meeting will be denied.

CMS policy requires that every foreign national (as defined by the Department of Homeland Security is "an individual who is a citizen of any country other than the United States") is assigned a host (in accordance with the Department Foreign Visitor Management Policy, Appendix C, Guidelines for Hosts and Escorts). The host/hosting official is required to inform the Division of Critical Infrastructure Protection (DCIP) at least 12 business days in advance of any visit

by a foreign national. Foreign nationals will be required to produce a valid passport at the time of entry.

Attendees that are foreign nationals need to identify themselves as such, and provide the following information for security clearance to the public meeting coordinator by the date specified in the **DATES** section of this notice:

- Visitor's full name (as it appears on passport).
- Gender.
- Country of origin and citizenship.
- Biographical data and related information.
- Date of birth.
- Place of birth.
- Passport number.
- Passport issue date.
- Passport expiration date.
- Dates of visits.
- Company Name.
- Position/Title.

Dated: February 13, 2012.

**Marilyn Tavenner**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2012-3969 Filed 2-23-12; 8:45 am]

**BILLING CODE 4120-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Medicare & Medicaid Services

[CMS-3259-PN]

##### Medicare Program; Application by the American Association of Diabetes Educators (AADE) for Continued Recognition as a National Accreditation Organization for Accrediting Entities To Furnish Outpatient 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 Association of Diabetes Educators for continued recognition as a national accreditation program for accrediting entities that wish to furnish outpatient diabetes self-management training to Medicare beneficiaries. The statute requires that we publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least 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 26, 2012.

**ADDRESSES:** In commenting, please refer to file code CMS-3259-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-3259-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.

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-3259-PN, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of 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, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

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

**FOR FURTHER INFORMATION CONTACT:** Jacqueline Leach, (410) 786-4282.

Kristin Shifflett, (410) 786-4133. Maria Hammel, (410) 786-1775.

**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 accreditation organization must have an agreement in effect with 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 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).

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.
- 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 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 we recognize an accreditation organization in this manner, any entity accredited by the national accreditation body's CMS-approved program for that service will be "deemed" to meet the Medicare conditions for coverage.

## II. Provisions of the Proposed Notice

The purpose of this notice is to notify the public of the American Association of Diabetes Educators' (AADE) request for the Secretary's approval of its accreditation program for outpatient DSMT services. The AADE submitted all the necessary materials to enable us to make a determination concerning its request for re-approval as a deeming organization for DSMTs. AADE was initially accredited on March 27, 2009, for a period of 3 years. This application was determined to be complete on January 13, 2012. This notice also solicits public comments on the ability of the AADE to continue to develop standards that meet or exceed the Medicare conditions for coverage, and apply them to entities furnishing outpatient DSMT.

### *Conditions for Coverage and Requirements for Outpatient Diabetes Self-Management Training 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 national 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 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 decision making process, and interviewing the organization's staff.

### *Notice Upon Completion of Evaluation*

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.

### **III. 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.

### **IV. 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.

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

Dated: February 10, 2012.

**Marilyn Tavenner,**

*Acting CMS Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2012-4277 Filed 2-23-12; 8:45 am]

**BILLING CODE 4120-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2012-N-0145]

### **Agency Information Collection Activities; Proposed Collection; Comment Request; Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey entitled "Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities." The data collection will obtain knowledge of State and local capacities including food safety defense staffing and expertise, laboratory capacities, and information systems to support food and feed safety and defense.

**DATES:** Submit either electronic or written comments on the collection of information by April 24, 2012.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850, 301-796-7726, [Ila.Mizrachi@fda.hhs.gov](mailto:Ila.Mizrachi@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

### **Improving Food Safety and Defense Capacity at the State and Local Level: Review of State and Local Capacities—(OMB Control Number 0910—New)**

The Food Safety Modernization Act (FSMA) (Pub. L. 111-353) states that a review must be conducted to assess the State and local capacities to show needs for enhancement in the areas or staffing levels, laboratory capacities, and information technology systems. This mandate is referenced again in FSMA section 110 stating that a review of current food safety and food defense capabilities must be presented to Congress no later than 2 years after the date of enactment (enactment date January 4, 2011). In order to facilitate this review, this team must distribute a