

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]

BILLING CODE 4120-01-P

## 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.

3. *By express or overnight mail.* You may send 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, 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 (one original and two copies) before the close of the comment period to one of the following addresses:

a. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201

(Because access to the interior of the HHH 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. 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 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:** Sue Bradshaw, (410) 786-2896.

**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 prescription drug benefits through a Prescription drug plan (PDP) sponsor that has a prescription drug plan contract with the Centers for Medicare & Medicaid Services (CMS). The regulations specifying the Medicare requirements that must be met in order for a PDP sponsor to enter into a prescription drug plan contract with CMS are located at 42 CFR part 423. These requirements implement Part D of Title XVIII of the Social Security Act (the Act), which specifies the prescription drug benefits that a PDP sponsor must provide and the requirements that the organization must meet to be a PDP sponsor. Other relevant sections of the Act are parts A and B of Title XVIII and part A of Title XI of the Act, pertaining to the provision of services by Medicare certified providers and suppliers.

Generally, for an organization to enter into a PDP contract, the organization must be licensed by the State as a risk bearing organization as set forth at 42 CFR 423.504(b)(2) of our regulations. Additionally, the organization must file an application demonstrating that it meets other Medicare requirements in part 423 of our regulations. Following approval of the contract, we engage in routine monitoring and oversight audits of the PDP sponsors to ensure continuing compliance. The monitoring and oversight audit process is comprehensive and uses a written protocol that itemizes the Medicare requirements that the PDP sponsors must meet.

As an alternative for meeting some Medicare requirements, a PDP sponsor may be exempt from CMS monitoring of certain requirements in subsets listed in section 1860D-4(j) of the Act (cross-referencing section 1852(e)(4)(B) of the Act) as a result of a PDP sponsor's accreditation by a CMS-approved accrediting organization (AO). In essence, the Secretary "deems" that the PDP has met the Medicare requirements via its accreditation, based on a previous determination that the AO's standards are at least as stringent as Medicare requirements. As we specify at § 423.168(b)(2)(ii) of our regulations, the term for which an AO may be approved by CMS may not exceed 6 years. For continuing approval, the AO will have to re-apply to CMS. An organization that applies for PDP sponsor deeming authority is generally recognized by the industry as an entity that accredits PDP sponsors that are licensed as prescription drug plan sponsors. Section 1852(e)(4)(C) of the Act requires that

within 210 days of receipt of an application, the Secretary shall determine whether the applicant meets criteria specified in section 1865(b)(2) (redesignated in 2008 as section 1865(a)(2)) of the Act.

On October 14, 2008 URAC submitted to CMS an application for deeming authority with respect to Part D sponsors' compliance with the following PDP plan requirements, as set out at 42 CFR 423.165(b):

- Access to covered drugs;
- Confidentiality and accuracy of enrollee prescription drug records;
- Drug utilization management, quality assurance measure and systems, medication therapy management; and,
- The sponsors' programs to control fraud, waste and abuse. To be approved for deeming authority, an accrediting organization must demonstrate that its accreditation program requirements meet or exceed the Medicare requirements for which it is seeking the authority to deem compliance.

**II. Provisions of the Proposed Notice**

The purpose of this proposed notice is to notify the public of the application of the Utilization Review Accreditation Commission 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.

*Deeming Application Approval Process*

The application process for deeming authority includes a review of URAC's application in accordance with the criteria specified by our regulations at § 422.171(a). This includes, but is not limited to, the following:

- The equivalency of URAC's requirements for PDP sponsors to CMS's comparable PDP sponsor requirements.
- URAC's survey process, to determine the following:
  - + The frequency of surveys.
  - + The types of forms, guidelines, and instructions used by surveyors.
  - + Descriptions of the accreditation decision making process, deficiency notification and monitoring process, and compliance enforcement process.
- Detailed information about individuals who perform accreditation surveys including—
  - + Size and composition of the survey team;
  - + Education and experience requirements for the surveyors;
  - + In-service training required for surveyor personnel;

+ Surveyor performance evaluation systems; and

+ Conflict of interest policies relating to individuals in the survey and accreditation decision process.

- Descriptions of the organization's—
- + Data management and analysis system;
- + Policies and procedures for investigating and responding to complaints against accredited organizations; and
- + Types and categories of accreditation offered and PDP sponsors and MA organizations currently accredited within those types and categories.

In accordance with § 423.171(b) of our regulations, the applicant must provide documentation relating to the following:

- Its ability to provide data in a CMS compatible format.
- The adequacy of personnel and other resources necessary to perform the required surveys and other activities.
- Assurances that it will comply with ongoing responsibility requirements specified in § 423.168(c) of our regulations.

Additionally, the accrediting organization must provide CMS with the opportunity to observe its accreditation process on site at a managed care organization and must provide any other information that CMS requires to prepare for an onsite visit. These site visits will help to verify that the information presented in the application is correct and to make a determination on the application.

In accordance with section 1865(a)(3)(A) of the Act and our regulations at § 423.168(b)(1), this proposed notice solicits public comment on the ability of URAC's accreditation program to meet or exceed the Medicare requirements for PDP sponsors which it seeks authority to deem as being in compliance with such requirements. In accordance with § 423.168(b)(1)(iii), comments are due [at least 30] days after the date of publication of this proposed notice.

### 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 (44 U.S.C. Chapter 35).

### 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.

### V. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

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

Dated: February 13, 2009.

#### Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9-4320 Filed 2-26-09; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1497-N]

#### Medicare Program; Public Meetings in Calendar Year 2009 for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS) Coding and Payment Determinations

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the dates, time, and location of the Healthcare Common Procedure Coding System (HCPCS) public meetings to be held in calendar year 2009 to discuss our preliminary coding and payment determinations for all new public requests for revisions to the HCPCS. These meetings provide a forum for interested parties to make oral presentations or to submit written comments in response to preliminary coding and payment determinations. Discussion will be directed toward responses to our specific preliminary recommendations and will include all items on the public meeting agenda.

**DATES:** *Meeting Dates:* The following are the 2009 HCPCS public meeting dates:

1. Tuesday, April 28, 2009, 9 a.m. to 5 p.m., eastern daylight time (e.d.t.) (Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents).

2. Wednesday, April 29, 2009, 9 a.m. to 5 p.m., e.d.t. (Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents).

3. Tuesday, May 12, 2009, 9 a.m. to 5 p.m., e.d.t. (Supplies and Other).

4. Wednesday, May 13, 2009, 9 a.m. to 5 p.m., e.d.t. (Supplies and Other).

5. Wednesday, May 27, 2009, 9 a.m. to 5 p.m., e.d.t. (Orthotics and Prosthetics).

6. Thursday, May 28, 2009, 9 a.m. to 5 p.m., e.d.t. (Durable Medical Equipment (DME) and Accessories).

7. Thursday, July 9, 2009, 9 a.m. to 5 p.m., e.d.t. (Durable Medical Equipment (DME) and Accessories, including Negative Pressure Wound Therapy (NPWT) devices).

*Deadlines for Primary Speaker Registration and Presentation Materials:* The deadline for registering to be a primary speaker, and submitting materials and writings that will be used in support of an oral presentation are as follows:

- April 14, 2009 for the April 28 and 29, 2009 public meetings.
- April 28, 2009 for the May 12 and 13, 2009 public meetings.
- May 13, 2009 for the May 27 and 28, 2009 public meetings.
- June 25, 2009 for the July 9, 2009 public meeting.

*Deadlines for All Other Attendees Registration:* All individuals must register for each date that they plan on attending. The registration deadlines are different for each meeting. Registration deadlines are as follows:

- April 21, 2009 for the April 28 and 29, 2009 public meeting dates.
- May 5, 2009 for the May 12 and 13, 2009 public meeting dates.
- May 20, 2009 for the May 27 and 28, 2009 public meetings.
- July 2, 2009 for the July 9, 2009 public meeting.

*Deadlines for Requesting Special Accommodations:*

- April 14, 2009 for the April 28 and 29, 2009 public meeting dates.
- April 28, 2009 for the May 12 and 13, 2009 public meeting dates.
- May 13, 2009 for the May 27 and 28, 2009 public meetings.
- June 25, 2009 for the July 9, 2009 public meeting.

*Deadline for Submission of Written Comments:* Written comments must be received by the date of meeting at which a request is scheduled for discussion.

**ADDRESSES:** *Meeting Location:* The public meetings will be held in the main auditorium of the central building of the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.