

Medicare conditions. A national accrediting organization applying for deeming authority under part 488, subpart A must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at §§ 488.4 and 488.8(d)(3). The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued deeming authority every 6 years or sooner as determined by us.

## II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's: Requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(b)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of DNV's request for deeming authority for hospitals. This notice also solicits public comment on whether DNV's requirements meet or exceed the Medicare conditions of participation for hospitals.

## III. Evaluation of Deeming Authority Request

DNV submitted all the necessary materials to enable us to make a determination concerning its request for approval as a deeming organization for hospitals. This application was determined to be complete on March 12, 2008. Under Section 1865(b)(2) of the Act and our regulations at § 488.8 (Federal review of accrediting organizations), our review and evaluation of DNV will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of DNV's standards for a hospital as compared with Medicare's hospital conditions of participation.
- DNV's survey process to determine the following:
  - The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.
  - The comparability of DNV's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
- DNV's processes and procedures for monitoring a hospital found out of compliance with DNV's program requirements. These monitoring procedures are used only when DNV identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.7(d).
- DNV's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
- DNV's capacity to provide us with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.
- The adequacy of DNV's staff and other resources, and its financial viability.
- DNV's capacity to adequately fund required surveys.
- DNV's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.
- DNV's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

## IV. Response to Public Comments and Notice Upon Completion of Evaluation

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 final notice in the **Federal**

**Register** announcing the result of our evaluation.

## 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. 35).

## VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights of States, local or tribal governments.

**Authority:** Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 11, 2008.

**Kerry Weems,**

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

[FR Doc. E8-8266 Filed 4-24-08; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1557-N]

### Medicare Program; Meeting of the Practicing Physicians Advisory Council, May 19, 2008

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

**ACTION:** Notice.

**SUMMARY:** This notice announces a quarterly meeting of the Practicing Physicians Advisory Council (the Council). The Council will meet to discuss certain proposed changes in regulations and manual instructions related to physicians' services, as identified by the Secretary of Health and Human Services (the Secretary). This meeting is open to the public.

**DATES:** *Meeting Date:* Monday, May 19, 2008, from 8:30 a.m. to 5 p.m. d.s.t.

*Deadline for Registration without Oral Presentation:* Thursday, May 8, 2008, 12 noon, d.s.t.

*Deadline for Registration with Oral Presentations:* Monday, May 5, 2008, 12 noon, d.s.t.

*Deadline for Submission of Oral Remarks and Written Comments:* Wednesday, May 7, 2008, 12 noon, d.s.t.

*Deadline for Requesting Special Accommodations:* Monday, May 12, 2008, 12 noon, d.s.t.

**ADDRESSES:** *Meeting Location:* The meeting will be held in Room 705A in the Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

*Submission of Testimony:* Testimonies should be mailed to Kelly Buchanan, Designated Federal Official (DFO), Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop C4-13-07, Baltimore, MD 21244-1850, or contact the DFO via e-mail at [PPAC@cms.hhs.gov](mailto:PPAC@cms.hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Kelly Buchanan, DFO, (410) 786-6132, or e-mail [PPAC@cms.hhs.gov](mailto:PPAC@cms.hhs.gov). News media representatives must contact the CMS Press Office, (202) 690-6145. Please refer to the CMS Advisory Committees' Information Line (1-877-449-5659 toll free), (410) 786-9379 local) or the Internet at <http://www.cms.hhs.gov/home/regsguidance.asp> for additional information and updates on committee activities.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces the quarterly meeting of the Practicing Physicians Advisory Council (the Council). The Secretary is mandated by section 1868(a)(1) of the Social Security Act (the Act) to appoint a Practicing Physicians Advisory Council based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and manual instructions related to physician services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the Council's consultation must occur before **Federal Register** publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) not later than December 31 of each year.

The Council consists of 15 physicians, including the Chair. Members of the

Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members of the Council must be physicians as described in section 1861(r)(1) of the Act; that is, State-licensed doctors of medicine or osteopathy. The remaining 4 members may include dentists, podiatrists, optometrists, and chiropractors. Members serve for overlapping 4-year terms.

Section 1868(a)(2) of the Act provides that the Council meet quarterly to discuss certain proposed changes in regulations and manual issuances that relate to physicians' services, identified by the Secretary. Section 1868(a)(3) of the Act provides for payment of expenses and per diem for Council members in the same manner as members of other advisory committees appointed by the Secretary. In addition to making these payments, the Department of Health and Human Services and CMS provide management and support services to the Council. The Secretary will appoint new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs in a manner to ensure appropriate balance of the Council's membership.

The Council held its first meeting on May 11, 1992. The current members are: Vincent J. Bufalino, M.D., Chairperson; M. Leroy Sprang, M.D.; Karen S. Williams, M.D.; Jonathon E. Siff, M.D., MBA; John E. Arradondo, M.D., MPH; Tye J. Ouzounian, M.D.; Arthur D. Snow, Jr., M.D.; Gregory J. Przybylski, M.D.; Jeffrey A. Ross, DPM, M.D.; and Roger L. Jordan, O.D. Four new members to be sworn on May 19th include: Joseph Giaimo, D.O.; Pamela Howard, M.D.; Fredrica Smith, M.D.; and Christopher Standaert, M.D.

##### **II. Meeting Format and Agenda**

The meeting will commence with the Council's Executive Director providing a status report, and the CMS responses to the recommendations made by the Council at the March 3, 2008 meeting, as well as prior meeting recommendations. Additionally, an update will be provided on the Physician Regulatory Issues Team. In accordance with the Council charter, we are requesting assistance with the following agenda topics:

- Recovery Audit Contractors (RAC) Update.
- National Provider Identifier (NPI) Update.
- CMS Quality Agenda, which includes the following:

- 9th Scope of Work.
- Physician Quality Reporting Initiative (PQRI) Update.
- Quality Measures: Hospital Compare; Nursing Home Compare.

For additional information and clarification on these topics, contact the DFO as provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual physicians or medical organizations that represent physicians wishing to present a 5-minute oral testimony on agenda issues must register with the DFO by the date listed in the **DATES** section of this notice. Testimony is limited to agenda topics only. The number of oral testimonies may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to the DFO for distribution to Council members for review before the meeting by the date listed in the **DATES** section of this notice. Physicians and medical organizations not scheduled to speak may also submit written comments to the DFO for distribution by the date listed in the **DATES** section of this notice.

##### **III. Meeting Registration and Security Information**

The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting the DFO at the address listed in the **ADDRESSES** section of this notice or by telephone at (410) 786-6132 by the date specified in the **DATES** section of this notice.

Since this meeting will be held in a Federal Government Building, the Hubert H. Humphrey Building, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to accommodate security procedures. In order to gain access to the building, participants will be required to show a government-issued photo identification (for example, driver's license or passport), and must be listed on an approved security list before persons are permitted entrance. Persons not registered in advance will not be permitted into the Hubert H. Humphrey Building and will not be permitted to attend the Council meeting.

All persons entering the building are subject to inspection via metal detector or other means applicable. In addition, all items brought to the Hubert H. Humphrey Building, whether personal or for the purpose of presentation, are subject to inspection. 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 the purpose of presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the DFO via the contact information specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

**Authority:** (Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92-463 (5 U.S.C. App. 2, section 10(a)).)

Dated: April 4, 2008.

**Kerry Weems,**

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

[FR Doc. E8-8231 Filed 4-24-08; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

*Title:* State Plan for Child Support under Title IV-D of the Social Security Act (OCSE-100 and OCSE-21-U4).

*OMB No.:* 0970-0017.

*Description:* The State plan preprint pages and amendments serve as a contract between the Office of Child Support Enforcement and State and Territory IV-D agencies. These State plan preprint pages and amendments outline the activities States and Territories will perform as required by law, in Section 454 of the Social Security Act, in order for States and Territories to receive Federal funds to meet the costs of child support enforcement.

*Respondents:* State and Territory IV-D Agencies.

#### ANNUAL BURDEN ESTIMATES

| Instrument                  | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|-----------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| State Plan (OCSE-100) ..... | 54                    | 1                                  | 0.5                               | 216                |
| OCSE-21-U4 .....            | 54                    | 1                                  | 0.25                              | 108                |

*Estimated Total Annual Burden Hours:* 324.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: April 15, 2008.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. E8-9040 Filed 4-24-08; 8:45 am]

**BILLING CODE 4184-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0030] (formerly Docket No. 2004D-0466)

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by May 27, 2008.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to [baguilar@omb.eop.gov](mailto:baguilar@omb.eop.gov). All comments should be identified with the OMB control number 0910-NEW and title,

“Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act.” Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act—(OMB Control Number 0910-NEW)

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(6)) requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the statement is truthful and not misleading. The draft guidance document entitled “Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act” (November 9,