

encourage nominations of qualified candidates from those groups.

The Secretary, or his designee, will appoint new members to the Panel from among those candidates determined to have the required expertise; new appointments will be done in a manner that will ensure an appropriate balance of membership.

II. Criteria for Nominees

Qualified nominees will meet those requirements necessary to be a Panel member. Panel members must be full-time employees and representatives of Medicare providers subject to the OPPS, with technical and/or clinical expertise in any of the following areas:

- Hospital payment systems.
- Hospital medical care delivery systems.
- Outpatient payment requirements.
- Ambulatory payment classification groups.
- Use of, and payment for, drugs and medical devices in an outpatient setting.
- Provision of, and payment for, partial hospitalization services.
- Any other relevant expertise.

It is not necessary that any nominee possess expertise in all of the areas listed, but each must have a minimum of 5 years experience and currently be employed full-time in his or her area of expertise. (**Please Note:** Consultants do not qualify for Panel membership under the nominee criteria.)

Members of the Panel serve overlapping 4-year terms, contingent upon the rechartering of the Panel on or before November 21, 2004.

Any interested person may nominate one or more qualified individuals. Self-nominations will also be accepted. Each nomination must include a letter of nomination, a curriculum vita of the nominee, and a statement from the nominee that the nominee is willing to serve on the Panel under the conditions described in this notice and further specified in the Charter.

III. Copies of the Charter

You may obtain a copy of the charter for the Panel by submitting a request to: Shirl Ackerman-Ross, CMS, Center for Medicare Management, Hospital & Ambulatory Policy Group, Division of Outpatient Care, 7500 Security Boulevard, Mail Stop C4-05-17, Baltimore, MD 21244, by telephone at (410) 786-4474 or by e-mail to SAckermanross@cms.hhs.gov. A copy of the charter is also available on the Internet at <http://www.cms.hhs.gov/faca>.

Authority: Section 1833(t)(9)(A) of the Social Security Act (42 U.S.C. 13951(t)(9)(A)) and Pub. L. 92-463 (5 U.S.C. App. 2).

Dated: January 16, 2004.

Dennis G. Smith,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1362-N]

Medicare Program; February 23-24, 2004, Meeting of the Practicing Physicians Advisory Council

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

ACTION: Notice.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council (the Council). The Council will be meeting to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary of the Department of Health and Human Services (the Secretary). These meetings are open to the public.

Meeting Registration: Persons wishing to attend this meeting must register for the meeting at least 72 hours in advance by contacting the Council Administrative Officer, Cheryl Slay, at cslay@cms.hhs.gov or (410)-786-7054. Persons who are not registered in advance will not be permitted into the Humphrey Building and thus will not be able to attend the meeting. Persons attending the meeting will be required to show a photographic identification, preferably a valid driver's license, before entering the building.

DATES: The meeting is scheduled for February 23, and February 24, 2004 from 8:30 a.m. until 5 p.m. e.s.t.

ADDRESSES: The meeting will be held in Room 800, at the Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Kenneth Simon, M.D., Executive Director, Practicing Physicians Advisory Council, 7500 Security Boulevard, Mail Stop C4-11-27, Baltimore, MD 21244-1850, (410) 786-3377. Please refer to the CMS Advisory Committees Information Line: (1-877-449-5659 toll free)/(410-786-9379 local) or the Internet at <http://cms.hhs.gov/faca/ppac/default.asp> for additional information and updates on committee activities.

News media representatives should contact the CMS Press Office, (202) 690-6145.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act (the Act) to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before 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 not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 of the members of the Council must be physicians described in section 1861(r)(1) of the Act; that is, State-licensed doctors of medicine or osteopathy. The remaining members may include dentists, podiatrists, optometrists, and chiropractors. Members serve for overlapping 4-year terms; terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before its termination. Section 1868(a) of the Act provides that nominations to the Secretary for Council membership must be made by medical organizations representing physicians.

The Council held its first meeting on May 11, 1992. The current members are: James Bergeron, M.D.; Ronald Castellanos, M.D.; Rebecca Gaughan, M.D.; Carlos R. Hamilton, M.D.; Joseph Heyman, M.D.; Dennis K. Iglar, M.D.; Joe Johnson, D.O.; Christopher Leggett, M.D.; Barbara McAneny, M.D.; Angelynn L. Moultrie-Lizana, D.O.; Laura B. Powers, M.D.; Michael T. Rapp, M.D. (Council Chair); Amilu Rothhammer, M.D.; Robert L. Urata, M.D.; and Douglas L. Wood, M.D.

Council members will be updated on the status of recommendations made. The agenda will provide for discussion and comment on the following topics:

- 2004 Physician Fee Schedule.
- Physicians Regulatory Issues Team Update.

- Sustainable Growth Rate.
- Medicare Prescription Drug Improvement and Modernization Act of 2003.
- Emergency Medical Treatment and Active Labor Act.
- End Stage Renal Disease Quality Initiative.
- Current Procedural Terminology (CPT) Codes and Evaluation & Management.
- Adjusted Wholesale Pricing.
- Outcome and Assessment Information Set and Home Care Benefits.

For additional information and clarification on the topics listed, call the contact person in the "For Further Information Contact" section of this notice.

Individual physicians or medical organizations that represent physicians wishing to make 5-minute oral presentations on agenda issues must contact the Executive Director by 12 noon, Friday, February 13, 2004, to be scheduled. Testimony is limited to agenda topics. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to Cheryl Slay at cslay@cms.hhs.gov no later than 12 noon, Friday, February 13, 2004, for distribution to Council members for review before the meeting. Physicians and organizations not scheduled to speak may also submit written comments to the Executive Director and Council members. The meeting is open to the public, but attendance is limited to the space available. Individuals requiring sign language interpretation or other special accommodation must contact Cheryl Slay at cslay@cms.hhs.gov or (410) 786-7054 at least 10 days before the meeting.

Authority: (Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Public Law 92-463 (5 U.S.C. App. 2, section 10(a)); 45 C.F.R. Part 11) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 13, 2004.

Dennis G. Smith,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0397]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Threshold of Regulation for Substances Used In Food-Contact Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below 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 February 23, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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.

Threshold of Regulation for Substances Used In Food-Contact Articles—(OMB Control Number 0910-0298)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j) of the act, (2) it conforms to the terms of a regulation prescribing its use, or (3) in the case of a food additive which meets the definition of a food-contact

substance in section 409(h)(6) of the act, there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made, (2) detailed information on the conditions of use of the substance, (3) a clear statement of the basis for the request for exemption from regulation as a food additive, (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance, (5) results of a literature search for toxicological data on the substance and its impurities, and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

In the **Federal Register** of September 16, 2003 (68 FR 54232), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden for this collection of information as follows: