

Additional background information can be found at: <http://www.cdc.gov/malaria/>.

Dated: April 4, 2005.

William P. Nichols,

*Director, Procurement and Grants Office,
Centers for Disease Control and Prevention.*

[FR Doc. 05-7047 Filed 4-7-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1296-N2]

Medicare Program; Request for Nominations to the Advisory Panel on Ambulatory Payment Classification Groups; Extension of Nominations Deadline

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

ACTION: Notice.

SUMMARY: This notice extends the deadline for nominations of members to the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the Panel). The original request for nominations was published in the *Federal Register* on February 25, 2005. (70 FR 9336) Six vacancies will exist on the Panel as of March 31, 2005.

The purpose of the Panel is to review the APC groups and their associated weights and to advise the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) concerning the clinical integrity of the APC groups and their associated weights. The advice provided by the Panel will be considered as CMS prepares its annual updates of the hospital Outpatient Prospective Payment System (OPPS) through rulemaking.

The panel was recently rechartered for a 2-year period through November 21, 2006.

Nominations: Nominations will be considered if received no later than May 9, 2005. Mail or deliver nominations to the following address: CMS; Attn: Shirl Ackerman-Ross, Designated Federal Officer (DFO), Advisory Panel on APC Groups; Center for Medicare Management (CMM), Hospital & Ambulatory Policy Group (HAPG), Division of Outpatient Care (DOC); 7500 Security Boulevard, Mail Stop C4-05-17; Baltimore, MD 21244-1850.

Web site: For additional information on the APC Panel and updates to the

Panel's activities, search our Web site at: <http://www.cms.hhs.gov/faca/apc/default.asp>.

Advisory Committees' Information Lines: You may also refer to the CMS Advisory Committee Information Hotlines at 1-877-449-5659 (toll-free) or 410-786-9379 (local) for additional information.

FOR FURTHER INFORMATION CONTACT:

Persons wishing to nominate individuals to serve on the Panel or to obtain further information can also contact Shirl Ackerman-Ross, the DFO, at APCPanel@cms.hhs.gov or call 410-786-4474. News media representatives should contact the CMS Press Office at 202-690-6145.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary is required by section 1833(t)(9)(A) of the Social Security Act (the Act), as amended and redesignated by sections 201(h) and 202(a)(2) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), respectively, to establish and consult with an expert, outside advisory panel on Ambulatory Payment Classification (APC) groups.

The Panel meets up to three times annually to review the APC groups and to provide technical advice to the Secretary and the Administrator concerning the clinical integrity of the groups and their associated weights. CMS considers the technical advice provided by the Panel as we prepare the proposed rule that proposes changes to the OPPS for the next calendar year.

The Panel may consist of up to 15 representatives who are full-time employees (not consultants) of Medicare providers, which are subject to the OPPS, and a Chair.

The Administrator selects the Panel membership based upon either self-nominations or nominations submitted by providers or interested organizations.

The current Panel members are: (The asterisk [*] indicates a Panel member whose term expires on March 31, 2005.)

- E.L. Hambrick, M.D., J.D., a CMS Medical Officer
- Marilyn K. Bedell, M.S., R.N., O.C.N.
- Albert Brooks Einstein, Jr., M.D.
- Lee H. Hilborne, M.D.*
- Stephen T. House, M.D.*
- Kathleen P. Kinslow, C.R.N.A., Ed.D.*
- Mike Metro, R.N.*
- Sandra J. Metzler, M.B.A., R.H.I.A.
- Gerald V. Naccarelli, M.D.*
- Frank G. Opelka, M.D.
- Louis Potters, M.D.

- Lou Ann Schraffenberger, M.B.A., R.H.I.A.
- Judie S. Snipes, R.N., M.B.A., C.H.E.
- Lynn R. Tomascik, R.N., M.S.N., C.N.A.A.

- Timothy Gene Tyler, Pharm.D.
- William A. Van Decker, M.D., J.D.*

Panel members serve without compensation, according to an advance written agreement; however, travel, meals, lodging, and related expenses are reimbursed in accordance with standard Government travel regulations. CMS has a special interest for ensuring that women, minorities, and the physically challenged are adequately represented on the Panel. CMS further encourages nominations of qualified candidates from those groups.

The Secretary, or his designee, appoints new members to the Panel from among those candidates determined to have the required expertise. New appointments are made in a manner that ensures a balanced membership.

II. Criteria for Nominees

All nominees must have technical expertise that enables them to participate fully in the work of the Panel. Such expertise encompasses hospital payment systems, hospital medical-care delivery systems, outpatient payment requirements, Ambulatory Payment Classification (APC) Groups, Physicians' Current Procedural Terminology Codes (CPTs), the use and payment of drugs and medical devices in the outpatient setting, and other forms of relevant expertise.

It is not necessary for a nominee to 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. Members of the Panel serve overlapping 2, 3, and 4-year terms, contingent upon the rechartering of the Panel.

Any interested person may nominate one or more qualified individuals. Self-nominations will also be accepted. Each nomination must include a letter of nomination, the 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

To obtain a copy of the Panel's Charter, submit a written request to the DFO at the address provided or by e-mail at APCPanel@cms.hhs.gov, or call her at 410-786-4474. Copies of the

Charter are also available on the Internet at <http://www.cms.hhs.gov/faca>.

Authority: Section 1833(t)(9)(A) of the Act (42 U.S.C. 13951(t)(9)(A)). The Panel is governed by the provisions of Pub. L. 92-463, as amended (5 U.S.C. Appendix 2).

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

Dated: March 31, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05-6862 Filed 4-7-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0564]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Temporary Marketing Permit Applications

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 9, 2005.

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 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.

Temporary Marketing Permit Applications—21 CFR 130.17(c) and (i) (OMB Control Number 0910-0133)—Extension

Section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341), directs FDA to issue regulations establishing definitions and standards of identity for food "[w]henver * * * such action will promote honesty and

fair dealing in the interest of consumers * * *". Under section 403(g) of the act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (21 CFR 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) enables the agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions and standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

In the **Federal Register** of January 13, 2005 (70 FR 2411), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total hours
130.17(c)	3	2	6	25	150
130.17(i)	4	2	8	2	16
Total					166

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated number of temporary marketing permit applications and hours per response is an average based on the agency's experience with applications received October 1, 2001, through September 30, 2004, and information from firms that have submitted recent requests for temporary marketing permits.

Dated: April 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-7021 Filed 4-7-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0565]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Petitions for Exemption From Preemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing

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