

Place: National Institutes of Health, Building 10, 10 Center Drive, Conference Room 9S235, Bethesda, MD 20892.

Time: May 14, 2010, 8:15 a.m. to 3 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 10, 10 Center Drive, Conference Room 9S235, Bethesda, MD 20892.

Contact Person: Ira W. Levin, PhD, Director, Division of Intramural Research, National Institute of Diabetes and Digestive and Kidney Diseases, NIH, Bethesda, MD 20892. 301-496-6844. iwl@helix.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 18, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-6675 Filed 3-25-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1570-N]

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

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice solicits nominations of five new members to the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the Panel). There will be five vacancies on the Panel as of September 30, 2010.

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 (DHHS) and the Administrator of the Centers for Medicare & Medicaid Services (CMS), concerning the clinical integrity of the APC groups and their associated weights.

The Secretary re-chartered the Panel in 2008 for a 2-year period effective through November 21, 2010.

DATES: Submission of Nominations: We will consider nominations if they are received no later than 5 p.m. (e.s.t.), May 26, 2010.

ADDRESSES: Please mail or hand deliver nominations to the following address: Centers for Medicare & Medicaid Services; Attn: Shirl Ackerman-Ross, Designated Federal Official (DFO), Advisory Panel on APC Groups; Center for Medicare Management, Hospital & Ambulatory Policy Group, Division of Outpatient Care; 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, we refer readers to view our website at the following: http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage. (Use control + click the mouse in order to access the previous URL.) (**Note:** There is an underscore after FACA/05_; there is no space.)

FOR FURTHER INFORMATION CONTACT:

Contact: Persons wishing to nominate individuals to serve on the Panel or to obtain further information may also contact Shirl Ackerman-Ross, the DFO, at CMSAPCPanel@cms.hhs.gov (**Note:** There is no underscore in this e-mail address; there is a SPACE between CMS and APCPanel.), or e-mail the DFO at Sackermanross@cms.hhs.gov.

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

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) to consult with an expert outside advisory Panel regarding the clinical integrity of the APC groups and relative payment weights that are components of the Medicare hospital Outpatient Prospective Payment System (OPPS).

The Charter requires that the Panel meet up to three times annually. CMS

considers the technical advice provided by the Panel as we prepare the proposed and final rules to update the OPPS for the next calendar year.

The Panel may consist of a chair and up to 15 members who are full-time employees of hospitals, hospital systems, or other Medicare providers that are subject to the OPPS. (For purposes of the Panel, consultants or independent contractors are not considered to be full-time employees in these organizations.)

The current Panel members are as follows: (**Note:** The asterisks [*] indicate the Panel members whose terms end on September 30, 2010.)

- E. L. Hambrick, M.D., J.D., Chair, a CMS Medical Officer
- Ruth L. Bush, M.D., M.P.H.
- Dawn L. Francis, M.D., M.H.S.
- Kathleen M. Graham, R.N., MSHA, CPHQ
- Patrick A. Grusenmeyer, Sc.D., FACHE
- David Halsey, M.D.
- Judith T. Kelly, B.S.H.A., RHIT, RHIA, CCS
- Michael D. Mills, Ph.D.*
- Agatha L. Nolen, D.Ph., M.S., FASHP
- Randall A. Oyer, M.D.
- Beverly Khnie Philip, M.D.*
- Daniel Pothen, M.S., RHIA, CPHIMS, CCS, CCS-P, CHC
- Gregory J. Przybylski, M.D.
- Russ Ranallo, M.S., B.S.*
- Michael A. Ross, M.D., FACEP*
- Patricia Spencer-Gisek, M.S., APRN-BC, AOCN®*

Panel members serve without compensation, according to an advance written agreement. However, for the meetings, CMS reimburses travel, meals, lodging, and related expenses in accordance with standard Government travel regulations.

CMS has a special interest in attempting to ensure, while taking into account the nominee pool, that the Panel is diverse in all respects of the following: Geography; rural or urban practice; race, ethnicity, sex, and disability; medical or technical specialty; and type of hospital, hospital health system, or other Medicare provider subject to the OPPS.

Based upon either self-nominations or nominations submitted by providers or interested organizations, the Secretary, or his or her 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 under the guidelines of the Federal Advisory Committee Act.

II. Criteria for Nominees

The Panel must be fairly balanced in its membership in terms of the points of view represented and the functions to be performed. The Panel shall consist of up to 15 members who are representatives of providers. Each Panel member must be employed full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPSS. All members must have technical expertise to enable them to participate fully in the Panel's work. Such expertise encompasses hospital payment systems; hospital medical care delivery systems; provider billing systems; APC groups; Current Procedural Terminology codes; and alpha-numeric Health Care Common Procedure Coding System codes; and the use of, and payment for, drugs and medical devices, as well as 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 have full-time employment in his or her area of expertise. Generally, members of the Panel serve overlapping terms of 4 years, based on the needs of the Panel and contingent upon the re-chartering of the Panel.

Any interested person or organization may nominate one or more qualified individuals. Self-nominations will also be accepted. Each nomination must include the following:

- Letter of Nomination,
- Curriculum Vitae of the nominee, and
- Written 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 in the **ADDRESSES** section or by e-mail at CMSAPCPanel@cms.hhs.gov, or call 410-786-4474.

Copies of the Charter are also available on the Internet at the following: <http://www.cms.hhs.gov/FACA/05AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage>.

IV. 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).

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

Dated: March 18, 2010.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2010-6789 Filed 3-25-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0141]

Small Entity Compliance Guide: Bottled Water: Total Coliform and *E. coli*; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Bottled Water: Total Coliform and *E. coli*—Small Entity Compliance Guide" for a final rule published in the **Federal Register** of May 29, 2009. This small entity compliance guide (SECG) is intended to set forth in plain language the requirements of the regulation and to help small businesses understand the regulation.

DATES: Submit electronic or written comments on the SECG at any time.

ADDRESSES: Submit electronic comments on the SECG to <http://www.regulations.gov>. Submit written comments on the SECG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the SECG to the Division of Plant and Dairy Food Safety (HFS-317), Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301-436-2651. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1639.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 29, 2009 (74 FR 25651), FDA issued a final rule amending its bottled water regulations to require that bottled water manufacturers test source water for total coliform, as is required for finished bottled water products, and to require, if any coliform organisms are detected in source water, that bottled water manufacturers determine whether any of the coliform organisms are *Escherichia coli* (*E. coli*), an indicator of fecal contamination. FDA also amended its bottled water regulations to require, if any coliform organisms are detected in finished bottled water products, that bottled water manufacturers determine whether any of the coliform organisms are *E. coli*. FDA also amended the adulteration provision of the bottled water standard to reflect the possibility of adulteration caused by the presence of filth. Under the amended regulations, bottled water containing *E. coli* will be considered adulterated, and source water containing *E. coli* will not be considered to be of a safe, sanitary quality and will be prohibited from use in the production of bottled water. FDA also amended its bottled water regulations to require that, before a bottler can use source water from a source that has tested positive for *E. coli*, the bottler must take appropriate measures to rectify or eliminate the cause of *E. coli* contamination of that source, and that the bottler must keep records of such actions. Existing regulatory provisions require bottled water manufacturers to keep records of new testing required by this rule. The effective date of the final rule is December 1, 2009.

FDA examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). Because the costs per entity of this rule are small, the agency believes that the final rule will not have a significant economic impact on a substantial number of small entities. However, FDA could not certify that the final rule would not have a significant economic impact on a substantial number of small entities. Therefore, in compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121), FDA is making available this SECG stating in plain language the legal requirements of the May 29, 2009, final rule set forth in 21 CFR parts 129 and 165 concerning the monitoring requirements for total coliform and *E. coli* in source water and finished bottled water products, the allowable levels of total coliform and *E.*