

I. Background

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act), and section 222 of the Public Health Service Act (PHS Act) to consult with an expert outside advisory panel regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights that are components of the Medicare Hospital Outpatient Prospective Payment System (OPPS), and the appropriate supervision level for hospital outpatient services. The Panel is governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92-463), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels. The panel may consider data collected or developed by entities and organizations (other than the Department of Health and Human Services) as part of their deliberations.

The Charter requires that the Panel meet up to three times annually. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the OPPS for the following calendar year.

The Panel shall consist of a chair and up to 19 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 asterisk [*] indicates the Panel members whose terms end effective September 30, 2013.)

- E.L. Hambrick, M.D., J.D., Chair, a CMS Medical Officer.
- Karen Borman, M.D.
- Ruth L. Bush, M.D., M.P.H.*
- Lanny Copeland, M.D.
- Kari S. Cornicelli, C.P.A., FHFMA
- Dawn L. Francis, M.D., M.H.S.*
- David A. Halsey, M.D.*
- Brain D. Kavanagh, M.D., M.P.H.
- Scott Manaker, M.D., Ph.D.
- John Marshall, CRA, RCC, RT
- Jim Nelson
- Leah Osbahr
- Jacqueline Phillips
- Daniel J. Pothien, M.S., RHIA, CHPS, CPHIMS, CCS, CCS-P, CHC*
- Gregory J. Przybylski, M.D.*
- Traci Rabine
- Michael Rabovsky, M.D.
- Marianna V. Spanki-Varelas M.D., Ph.D., M.B.A.
- Gale Walker
- Kris Zimmer

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 ensuring, 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 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 FACA guidelines.

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. Each Panel member must be employed full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPPS. 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, medical devices, and other services in the outpatient setting, as well as other forms of relevant expertise. For supervision deliberations, the Panel shall have members that represent the interests of Critical Access Hospitals (CAHs), who advise CMS only regarding the level of supervision for hospital outpatient services.

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 up to 4 years, based on the needs of the Panel and contingent upon the rechartering of the Panel. A member may serve after the expiration of his or her term until a successor has been sworn in.

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 stating the reasons why the nominee should be considered.
- Curriculum vitae or resume of the nominee.
- Written and signed 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.
- The hospital or hospital system name and address, or CAH name and address, as well as all Medicare hospital and or Medicare CAH billing numbers of the facility where the nominee is employee.

III. Copies of the Charter

To obtain a copy of the Panel's Charter, we refer readers to our Web site at the following: <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

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: October 29, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1161]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Safety Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the

PRA), Federal Agencies must publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information and allow 60 days for public comment. This notice invites comments on a voluntary consumer survey entitled, "Food Safety Survey."

DATES: Submit either written or electronic comments on the collection of information by December 31, 2013.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility;

(2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Safety Survey—(OMB Control Number 0910-0345)—Reinstatement

I. Background

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), we are authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. The Food Safety Survey measures consumers' knowledge, attitudes, and beliefs about food safety. Previous versions of the survey were collected in 1988, 1993, 1998, 2001, 2006, and 2010. Data from the previous Food Safety Surveys and from this proposed survey will be used to evaluate two Healthy People 2020 objectives: (1) Increase the proportion of consumers who follow key food safety practices (Objective FS-5), and (2) reduce severe allergic reactions to food among adults with a food allergy diagnosis (Objective FS-4) (Ref. 1). Data from this survey will also be used to measure progress toward the United States Department of Agriculture's Food Safety Inspection Service's FY2011-FY2016 Strategic Plan goal of ensuring that, "Consumers, including vulnerable and underserved populations, adopt food safety best practices" (Ref. 2). Additionally, Food Safety Survey data are used to measure trends in consumer food safety habits including hand and cutting board washing, cooking practices, and use of food thermometers. Finally, data are used to evaluate educational messages and to inform policymakers about consumer attitudes about technologies such as food irradiation and biotechnology.

The proposed Food Safety Survey will contain many of the same questions and topics as previous Food Safety Surveys to facilitate measuring trends in food

safety knowledge, attitudes, and behaviors over time. The proposed survey will also be updated to explore emerging consumer food safety topics and expand understanding of previously asked topics. For example, recent papers in both the United States (Ref. 3) and Europe (Refs. 4 and 5) have pointed to changing epidemiology of listeriosis where adults over 60 years old have the highest rates of the illness. One reason for the increase in listeriosis rates among those over 60 years old could be increasing host susceptibility due to widened use of immunocompromising medications. We plan to include questions on the proposed survey to document the proportion of those over 60 years old who self-report taking a defined list of major immunocompromising medications. In conjunction with our established questions about safe food handling and eating potentially risky foods, the additional questions will expand our understanding of listeriosis among those over 60. Other new topics planned to be covered on the survey include: Consumer understanding of mechanically tenderized beef, awareness of foodborne pathogens such as *Toxoplasma gondii*, and awareness of the risks associated with eating raw sprouts.

The methods for the proposed Food Safety Survey will be largely the same as those used with the previous Food Safety Surveys. One major difference is that, unlike the data collection mode for previous Food Safety Surveys that used only land telephone lines, the proposed survey will include cell phones in addition to landlines. A nationally representative sample of 4,000 adults (2,400 landline and 1,600 cell phone) will be selected at random for the telephone interviews. The survey will also include an oversample of Hispanics and Blacks to ensure a minimum of 400 each. Additionally, 50 non-respondents will be asked to participate in a short version of the survey from which we will conduct a non-response analysis. Participation in the survey will be voluntary. Cognitive interviews and a pre-test will be conducted prior to fielding the survey.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener	75	1	75	0.083 (5 mins.)	6
Cognitive interview	9	1	9	1. (60 mins.)	9

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest screener	45	1	45	0.0167 (1 min.)	1
Pretest	18	1	18	0.33 (20 mins.)	6
Survey screener	10,000	1	10,000	0.0167 (1 min.)	167
Survey	4,000	1	4,000	0.33 (20 mins)	1320
Non-response survey screener	125	1	125	0.0167 (1 min.)	2
Non-response survey	50	1	50	0.1 (10 mins.)	5
Total					1516

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

FDA's burden estimate is based on the Agency's prior experience with the Food Safety Survey.

II. References

1. U.S. Department of Health and Human Services, "Healthy People 2020—Improving the Lives of Americans," July 30, 2013. Available at <http://www.healthypeople.gov/2020/default.aspx>.
2. U.S. Department of Agriculture, Food Safety Inspection Service, "Strategic Plan FY 2011–2016," April 6, 2012. Available at http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/strategic-planning/fy-2011-2016-strategic-plan/ct_index.
3. Pouillot, R., Hoelzer, K., Jackson, K.A., Henao, O.L. and Silk, B.J. "Relative Risk of Listeriosis in Foodborne Diseases Active Surveillance Network (FoodNet) Sites According to Age, Pregnancy, and Ethnicity," *Clinical Infectious Diseases*, 54(S5): S401–410, 2012.
4. Goulet, V., Hedberg, C., Le Monnier A. and de Valk, H. "Increasing Incidence of Listeriosis in France and other European Countries," *Emerging Infectious Diseases*, 14(5): 734–740, 2008.
5. Muñoz, P., Rojas, L., Bunsow, E., Saez, E., Sánchez-Cambrotero, L., Alcalá, L., Rogríquez-Creixems, M. and Bouza, E. "Listeriosis: An Emerging Public Health Problem Especially Among the Elderly," *Journal of Infection*, 64: 19–33, 2012.

Dated: October 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1155]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our food labeling regulations and on Form FDA 3570, Model Small Business Nutrition Labeling Exemption Notice, which small businesses may use to claim the small business exemption from nutrition labeling.

DATES: Submit either electronic or written comments on the collection of information by December 31, 2013.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR

1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Labeling Regulations—21 CFR Parts 101, 102, 104, and 105 (OMB Control Number 0910–0381)—Revision To Include Collections Previously Approved by OMB, but Currently in Use Without Approval

Our food labeling regulations require food producers to disclose to consumers and others specific information about themselves or their products on the label or labeling of their products. Related regulations require that food producers retain records establishing the basis for the information contained in the label or labeling of their products and provide those records to regulatory officials. Finally, certain regulations