

physicians, providers (including institutional providers like outpatient hospitals), practitioners (such as chiropractors), and suppliers, as well as hospice providers and Religious Non-medical Health Care Institutions paid under Part A. Home health agencies providing items and services under Part A or Part B also use the ABN. Other Medicare institutional providers paid under Part A use other approved notices for this purpose. With this PRA submission, minimal formatting changes have been made to the ABN form, including the addition of language informing beneficiaries of their rights under Section 504 of the Rehabilitation Act of 1973 (section 504) by alerting the beneficiary to CMS's nondiscrimination practices and the availability of alternate forms of this notice, if needed. Additionally, minor language and grammatical changes have been made to the form's instructions to improve provider/supplier comprehension and decrease the probability of errors in completing the ABN. There are no substantive changes to the form or to the instructions. *Form Number:* CMS-R-131 (OMB control number: 0938-0566; *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 1,499,910; *Total Annual Responses:* 62,910,000; *Total Annual Hours:* 7,339,710. (For policy questions regarding this collection contact Evelyn Blaemire at 410-786-1803).

Dated: November 4, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015-28449 Filed 11-6-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-906 and CMS-1771]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to

publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by December 9, 2015.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 OR, Email: *OIRA_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT:

Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. The term "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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* The Fiscal Soundness Reporting Requirements; *Use:* The CMS is assigned responsibility for overseeing all Medicare Advantage Organizations (MAOs), Prescription Drug Plan (PDP) sponsors and PACE organizations on-going financial performance. Specifically, CMS needs the requested collection of information to establish that contracting entities within those programs maintain fiscally sound organizations and thereby remain a going concern. All contracting organizations must submit annual independently audited financial statements one time per year. The MAOs with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth must file three quarterly financial statements. Currently, there are approximately 71 MAOs filing quarterly financial statements. Part D organizations must also file 3 quarterly financial statements. The PACE organizations are required to file 4 quarterly financial statements for the first three years in the program as well as PACE organizations with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth. *Form Number:* CMS-906 (OMB control number: 0938-0469); *Frequency:* Annually; *Affected Public:* Business or other for-profits; *Number of Respondents:* 815; *Total Annual Responses:* 1,518; *Total Annual Hours:* 506. (For policy questions regarding this collection contact GERALYN GLENN at 410-786-0973.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Emergency and Foreign Hospital Services; *Use:* Section 1866 of the Social Security Act states that any provider of services shall be qualified to participate in the Medicare program and shall be eligible for payments under Medicare if it files an agreement with the Secretary to meet the conditions outlined in this section of the Act. Section 1814 (d)(1) of

the Social Security Act and 42 CFR 424.100, allows payment of Medicare benefits for a Medicare beneficiary to a nonparticipating hospital that does not have an agreement in effect with the Centers for Medicare and Medicaid Services. These payments can be made if such services were emergency services and if CMS would be required to make the payment if the hospital had an agreement in effect and met the conditions of payment. This form is used in connection with claims for emergency hospital services provided by hospitals that do not have an agreement in effect under section 1866 of the Social Security Act. As specified in 42 CFR 424.103(b), before a non-participating hospital may be paid for emergency services rendered to a Medicare beneficiary, a statement must be submitted that is sufficiently comprehensive to support that an emergency existed. Form CMS-1771 contains a series of questions relating to the medical necessity of the emergency. The attending physician must attest that the hospitalization was required under the regulatory emergency definition and give clinical documentation to support the claim. A photocopy of the beneficiary's hospital records may be used in lieu of the CMS-1771 if the records contain all the information required by the form. *Form Number:* CMS-1771 (OMB control number: 0938-0023); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 100; *Total Annual Responses:* 200; *Total Annual Hours:* 50. (For policy questions regarding this collection contact Shauntari Cheely at 410-786-1818.)

Dated: November 4, 2015.

William N. Parham, III

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Food Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration

(FDA). The meeting will be open to the public.

Name of Committee: Food Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 7 and 8, 2015, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Karen Strambler, Center for Food Safety and Applied Nutrition, HFS-024, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, 240-402-2589, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The Food Advisory Committee will meet to discuss FDA's policies related to the presence of *Listeria monocytogenes* in foods.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written

submissions may be made to the contact person on or before November 20, 2015. Oral presentations from the public will be scheduled between approximately 11 a.m. to 12 p.m. on December 8, 2015. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 30, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 23, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Karen Strambler at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-28387 Filed 11-6-15; 8:45 am]

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