

pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-1856 and CMS-1893, CMS-10068 and CMS-265-11]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by August 8, 2014.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the

instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number __, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-1856 and CMS-1893 Request for Certification in the Medicare and/or Medicaid Program to Provide Outpatient Physical Therapy and/or Speech Pathology Services, and Outpatient Physical Therapy—Speech Pathology Survey Report

CMS-10068 Medicare Ombudsman Customer Service Feedback Survey

CMS-265-11 Independent Renal Dialysis Facility Cost Report Form

Under the Paperwork Reduction Act (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 requires Federal agencies to publish a

60-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.

Information Collection

1. *Type of Information Collection*

Request: Revision of a currently approved collection; *Title of Information Collection:* (CMS-1856) Request for Certification in the Medicare and/or Medicaid Program to Provide Outpatient Physical Therapy and/or Speech Pathology Services, and (CMS-1893) Outpatient Physical Therapy—Speech Pathology Survey Report; *Use:* Form CMS-1856 is used as an application to be completed by providers of outpatient physical therapy and/or speech-language pathology services requesting participation in the Medicare and Medicaid programs. This form initiates the process for obtaining a decision as to whether the conditions of participation are met as a provider of outpatient physical therapy, speech-language pathology services, or both. It is used by the State agencies to enter new providers into the Automated Survey Process Environment (ASPEN). Form CMS-1893 is used by the State survey agency to record data collected during an on-site survey of a provider of outpatient physical therapy and/or speech-language pathology services, to determine compliance with the applicable conditions of participation, and to report this information to the Federal government. The form is primarily a coding worksheet designed to facilitate data reduction and retrieval into the ASPEN system. The information needed to make certification decisions is available to us only through the use of information abstracted from the form.

Form Numbers: CMS-1856 and CMS-1893 (OMB control number: 0938-0065); *Frequency:* Annually, occasionally; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 700; *Total Annual Responses:* 700; *Total Annual Hours:* 613. (For policy questions regarding this collection contact James Cowher at 410-786-1948.)

2. *Type of Information Collection*

Request: Reinstatement with change of a previously approved collection; *Title of Information Collection:* Medicare Ombudsman Customer Service Feedback Survey; *Use:* The Centers for Medicare and Medicaid Services stresses a continuing need for setting

customer service goals that include providing accurate, timely, and relevant information to its customers. With these goals in mind, we periodically survey our customers to ensure that the needs of Medicare beneficiaries are being met. This survey will be used to measure overall satisfaction of the customer service that the Medicare Ombudsman Group (MOG) within CMS provides to Medicare beneficiaries and their representatives. The information provided will be used by management and staff to measure and improve the quality and timeliness of responses to written and verbal correspondence.

Form Numbers: CMS-10068 (OMB control number: 0938-0894); *Frequency:* Annually, occasionally; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 2,380; *Total Annual Responses:* 2,380; *Total Annual Hours:* 317. (For policy questions regarding this collection contact Nancy Conn at 410-786-8374.)

3. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Independent Renal Dialysis Facility Cost Report Form; **Use:** Providers of services participating in the Medicare program are required under sections 1815(a) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The Independent Renal Dialysis Facility Cost Report (Form CMS-265-11) cost report is needed to determine a provider's reasonable costs incurred in furnishing medical services to Medicare beneficiaries. The cost reports are required to be filed with the provider's Medicare Administrative Contractor (MAC). The functions of the MAC are described in section 1816 of the Social Security Act. However, the collection of data is a secondary function of the cost report. We use the data to support program operations, payment refinement activities, and to make Medicare Trust Fund projections.

Form Numbers: CMS-10068 (OMB control number: 0938-0894); *Frequency:* Annually, occasionally; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 2,380; *Total Annual Responses:* 2,380; *Total Annual Hours:* 317. (For policy questions regarding this collection contact Gail Duncan at 410-786-7278.)

Dated: June 3, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1164]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Testing Communications on Biological Products

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 July 9, 2014.

ADDRESSES: 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: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0687. Also include the FDA 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, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

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.

Testing Communications on Biological Products—(OMB Control Number 0910-0687)—Extension

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational

and public information programs relating to the safety of regulated biological products. FDA conducts needed research to help ensure that such programs have the highest likelihood of being effective. FDA expects that improving communications about biological products will involve many research methods, including individual in-depth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys. The information will be used to explore concepts of interest and assist in the development and modification of communication messages and campaigns to fulfill the Agency's mission to protect the public health.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about biological product use. Knowledge of consumer and health care professional decisionmaking processes will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, and labels. These communications will aim to improve public understanding of the risks and benefits of using biological products by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

In the **Federal Register** of October 1, 2013 (78 FR 60287), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information based on prior experience with the various types of data collection methods described in this document: