

private health plans. As part of this evaluation, qualitative and quantitative data will be collected and analyzed to answer research questions focused on: (1) State initiative features and implementation, including various payment models; (2) practice characteristics, particularly medical home transformation; and (3) outcomes, including access to and coordination of care, clinical quality of care and patient safety, beneficiary experience with care, patterns of utilization, Medicare and Medicaid expenditures, and budget neutrality. This information will help CMS decide whether the MAPCP Demonstration model should be expanded under Medicare, and if so, what modifications and supports would be needed to implement similar innovations in other states and practices in the future. *Form Number:* CMS-10436 (OCN: 0938-New); *Frequency:* Yearly; *Affected Public:* Individuals and households; *Number of Respondents:* 472; *Total Annual Responses:* 472; *Total Annual Hours:* 478 (For policy questions regarding this collection contact Suzanne Goodwin at 410-786-0226. For all other issues call 410-786-1326.)

**2. Type of Information Collection Request:** New collection; **Title of Information Collection:** Medicare Enrollment Application for Clinics/ Group Practice and Certain Other Suppliers; **Use:** The primary function of the CMS-855B enrollment application for Clinics, Group Practices and Certain Other Suppliers is to gather information from the organization that tells us what it is, whether it meets certain qualifications to be a health care supplier, where it renders services and information necessary to establish the correct claims payment. The goal of evaluating and revising the CMS-855B enrollment application is to simplify and clarify the information collection without jeopardizing our need to collect specific information. The majority of the revisions are very minor in nature such as spelling and formatting corrections, removal of duplicate fields and instruction clarification for the organization/group. The Sections and Sub-Sections within the form are also being re-numbered and re-sequenced to create a more logical flow of the data collection. In addition, CMS is adding a data collection for an address to mail the periodic request for the revalidation of enrollment information (only if it differs from other addresses currently collected). Other than the revalidation mailing address described above, new data being collected in this revision package is a checkbox indicating

whether or not an organization is wholly owned or operated by a hospital, the inclusion of a new supplier type (Centralized Flu Biller) and information on, if applicable, where the supplier stores its patient records electronically. *Form Number:* CMS-855B (OCN: 0938-New); *Frequency:* Yearly; *Affected Public:* Individuals and households; *Number of Respondents:* 31,000; *Total Annual Responses:* 31,000; *Total Annual Hours:* 103,000 (For policy questions regarding this collection contact Kim McPhillips at 410-786-5374. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office at (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by **July 30, 2012**:

1. *Electronically.* You may submit 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) 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.

Dated: May 25, 2012.

**Martique Jones,**

*Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-305]

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

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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 function; (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.

1. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* External Quality Review Protocols. *Use:* The results of Medicare reviews, Medicare accreditation services, and Medicaid external quality reviews will be used by States in assessing the quality of care provided to Medicaid beneficiaries by managed care organizations and to provide information on the quality of care provided to the general public upon request. Protocols 1, 2, 3, 4, 5, 7, and the External Quality Review Background have been revised since the publication of the 60-day **Federal Register** notice on February 17, 2012 (77 FR 9661). All of the revised protocols associated with the 60-day notice and this 30-day notice are in draft and must not be used until they are approved by OMB through the PRA process. *Form Number:* CMS-R-305 (OCN 0938-0786). *Frequency of Reporting:* Yearly. *Affected Public:* State, Local or Tribal Governments. *Number of Respondents:* 42. *Total Annual Responses:* 70. *Total Annual Hours:* 415,643. (For policy questions regarding this collection contact Gary B. Jackson at 410-786-

1218. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on July 2, 2012. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax Number: (202) 395-6974, Email: OIRA\_submission@omb.eop.gov.*

Dated: May 25, 2012.

**Martique Jones,**

*Director, Regulations Development Group, Division-B, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0495]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Declaration of Amount of Added Sugars**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study entitled "Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Declaration of Amount of Added Sugars."

**DATES:** Submit either electronic or written comments on the collection of information by July 30, 2012.

**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:** Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, *domini.bean@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 before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's 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.

#### **Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Declaration of Amount of Added Sugars—(OMB Control Number 0910-New)**

##### **I. Background**

Under the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535), the Nutrition Facts label is required on most packaged foods and this information must be provided in a specific format in accordance with the provisions of § 101.9 (21 CFR 101.9). When FDA was determining which Nutrition Facts label format to require, the Agency undertook consumer research to evaluate alternatives (Refs. 1 to 3). More recently, FDA conducted qualitative consumer research on the format of the Nutrition Facts label on behalf of the Agency's Obesity Working Group (Ref. 4), which was formed in 2003 and tasked with outlining a plan to help confront the problem of obesity in the United States (Ref. 5). In addition to conducting consumer research, in the **Federal Register** of November 2, 2007 (72 FR 62149) FDA issued an Advance Notice of Proposed Rulemaking (ANPRM) entitled, "Food Labeling: Revision of Reference Values and Mandatory Nutrients" (the 2007 ANPRM), which requested comments on a variety of topics related to a future proposed rule to update the presentation of nutrients and content of nutrient values on food labels. In the 2007 ANPRM, the Agency included a request for comments on how consumers use the percent Daily Value in the Nutrition Facts label when evaluating the nutritional content of food items and making purchases.

Research has suggested that consumers use the Nutrition Facts label in various ways, including, but not limited to, using the Nutrition Facts label to determine if products are high or low in a specific nutrient and to compare products (Ref. 6). One component of the Nutrition Facts label that serves as an aid in these uses is the percent Daily Value. Early consumer research indicated that the percent Daily Value format improved consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet (Ref. 3), which led FDA to require both quantitative and percentage declarations of nutrient Daily Values in the Nutrition Facts label in the 1993 Nutrition Labeling final rule (58 FR 2079, January 6, 1993).

Research in subsequent years, however, suggested that consumers' understanding and use of percent Daily Value may be somewhat inconsistent