

be submitted in one of the following ways by *August 27, 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: June 22, 2012.

Martique Jones,

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

[FR Doc. 2012-15694 Filed 6-26-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10429]

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:* New collection (request for a new OMB control number). *Title of Information Collection:* Surveys of Physicians and Home Health Agencies

to Assess Access Issues for Specific Medicare Beneficiaries as Defined in Section 3131(d) of the ACA. *Use:* This collection is part of a study called for under section 3131(d) of the Patient Protection and Affordable Care Act (ACA). The study is focused on two major issues: (1) supporting CMS' efforts to improve payment accuracy and (2) understanding issues of access for the ACA populations under the existing home health prospective payment system. The study team's analytic plan focuses on understanding payment accuracy for the specific study populations through claims and cost data analyses, which will reflect payments and costs for patients who have gained access to home health care. In order to understand access issues for the ACA defined populations, the study team proposes using survey instruments to better understand the characteristics of Medicare beneficiaries who are not able to gain access to or have experienced delays in gaining access to home health services.

As a new collection, the information collected is expected to support CMS' efforts to improve the home health prospective payment system payment accuracy for vulnerable populations and thereby ensure the payment system does not inadvertently cause avoidable access problems. The questions are designed to provide insights into access issues for vulnerable populations that cannot be learned through analyses of administrative data.

Form Number: CMS-10429 (OCN: 0938-New). *Frequency:* Once. *Affected Public:* Private Sector (business or other for-profit and not-for-profit institutions). *Number of Respondents:* 875. *Total Annual Responses:* 292. *Total Annual Hours:* 73. (For policy questions regarding this collection contact Kristy Chu at 410-786-8953. 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, 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 27, 2012*. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax

Number: (202) 395-6974, Email: OIRA_submission@omb.eop.gov.

Dated: June 22, 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

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Parents and Children Together. *OMB No.:* 0970-0403.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services is proposing an information collection activity as part of an evaluation of healthy marriage and responsible fatherhood grant programs. The evaluation study title is Parents and Children Together (PACT).

A 60-Day **Federal Register** Notice was published for this study on December 20, 2011. This Notice described all components of the study and, therefore, we request to waive additional 60-Day **Federal Register** Notices. This 30-Day **Federal Register** Notice covers (a) instruments for the impact study baseline survey (including an introductory script and the baseline survey itself), and (b) site Management Information Systems (MIS).

This information collection request is specific to Responsible Fatherhood programs that may be evaluated (requests specific to Healthy Marriage programs will be separate). The baseline survey will collect data related to such domains as father involvement, coparenting, parenting, marriage and romantic relationships, and employment. The information from the baseline survey will be used by ACF for, among other things, describing the populations served and determining the comparability of program and control groups. Information on participant entry, participation, and exit from the program will be entered into the MIS system.

Respondents: Baseline information will be collected from all fathers prior to random assignment; the introductory script will be read by program staff to fathers applying to the program. Program staff will record information on the services received by study

participants in the study Management Information System (MIS).

Annual Burden Estimates

The following table provides the combined burden estimates for the

previously-approved field data collection instrument, and the current request. Burden for all instruments is annualized over three years.

Activity/respondent	Annual number of respondents	Number of responses per respondent	Average burden per response (minutes)	Total annual burden hours
Collection of Field Data (Approved April 20, 2012)				
Selecting Study Grantees Discussions/grantee and partner organization staff	50	1	60	50
Introductory Script and Baseline Survey (Currently Requested)				
Introductory Script:				
(1) Grantee staff	30	70.2	10	351
(2) Program applicants	2,105	1	10	351
Baseline Survey:				
(1) Study participants	2,000	1	30	1,000
Study MIS (Currently Requested)				
Study MIS:				
(1) Grantee staff	30	2,517	2	2,517

Estimated Total Annual Burden Hours: 4,269.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: OPREinfocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA.SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Steven M. Hanmer,

Reports Clearance, Officer.

[FR Doc. 2012-15440 Filed 6-26-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0747]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form and Type A Medicated Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form and Type A Medicated Articles" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, Juanmanuel.Vilela@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On March 19, 2012, the Agency submitted a proposed collection of information entitled "Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form and Type A Medicated

Articles" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0575. The approval expires on June 30, 2015. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: June 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-15721 Filed 6-26-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0357]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Decision Analysis: A Risk-Tolerance Pilot Study

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