

standards used to set payment rates, and provide a basis for FFP, when the proposed plan did not specify the amount or methodology to determine a key variable that would determine the rate (a “conversion factor”); and

- Whether CMS incorrectly disapproved SPA 08–003 on September 23, 2008, by means of a hardcopy, date-stamped, signed letter from the CMS Acting Administrator, with a courtesy electronic copy of the signed letter e-mailed to Montana on September 24, 2008.

Section 1116 of the Act and Federal regulations at 42 CFR Part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. CMS is required to publish a copy of the notice to a State Medicaid agency that informs the agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Montana announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. Mary E. Dalton,
Acting Medicaid Director,
Montana DPHHS,
Helena, MT 59604–4210.

Dear Ms. Dalton:

I am responding to your request for reconsideration of the decision to disapprove the Montana State plan amendment (SPA) 08–003, which was submitted on December 27, 2007, and disapproved on September 23, 2008. The SPA proposed to modify the reimbursement methodology for licensed denturist services and dental services effective October 1, 2007.

The issues to be considered at the hearing are:

- Whether Montana’s proposed methodologies for payment of dental and denturist services, meet the requirements of section 1902(a)(30)(A) of the Social Security Act and Federal regulations at 42 CFR 430.10 and 42 CFR 447.252(b), which require that the State plan include a comprehensive description of the methods and standards used to set payment rates, and provide a basis for Federal financial participation, when the proposed plan did not specify the amount or methodology to determine a key variable that would determine the rate (a “conversion factor”); and

- Whether CMS incorrectly disapproved SPA 08–003 on September 23, 2008, by means of a hardcopy, date-stamped, signed letter from the CMS Acting Administrator, with a courtesy electronic copy of the signed letter e-mailed to Montana on September 24, 2008.

I am scheduling a hearing on your request for reconsideration to be held on January 27, 2009, at the CMS Denver Regional Office, 1600 Broadway, Suite 700, Denver, Colorado 80202, in order to reconsider the decision to disapprove SPA 08–003. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by Federal regulations at 42 CFR Part 430.

I am designating Mr. Benjamin Cohen as the presiding officer. If these arrangements present any problems, please contact the presiding officer at (410) 786–3169. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing.

Sincerely,

Kerry Weems,

Acting Administrator.

Section 1116 of the Social Security Act (42 U.S.C. 1316; 42 CFR 430.18).

(Catalog of Federal Domestic Assistance program No. 13.714, Medicaid Assistance Program.)

Dated: December 22, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–30820 Filed 12–24–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Head Start Facilities Construction, Purchase and Major Renovation—45 CFR part 1309.

OMB No.: 0970–0193.

Description: The Head Start Bureau is proposing to renew, without changes, 45 CFR part 1309. This rule contains the administrative requirements for Head Start and Early Head Start grantees who apply for funding to purchase, renovate, or construct Head Start program facilities. The rule ensures that grantees use standard business practices when acquiring real property and that Federal interest is preserved in properties acquired with public funds. The rule further ensures compliance with all other Federal statutes applicable to the expenditure of Federal funds when acquiring real property.

Respondents: Head Start and Early Head Start grantees and delegate agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Regulation	200	1	41	8,200

Estimated Total Annual Burden Hours: 8,200.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L’Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address:

infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have

practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 22, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8-30832 Filed 12-24-08; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Performance Measures for Healthy Marriage and Promoting Responsible Fatherhood Grant Programs.

OMB No.: New Collection.

Description: The Office of Family Assistance (OFA), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), intends to request approval from the Office of Management and Budget (OMB) for the collection of performance measures from grantees for the Healthy Marriage and Promoting Responsible Fatherhood discretionary grant programs. The performance measure data obtained from the grantees will be used by OFA to report on the

overall performance of this grant program and to inform the Program Assessment Rating Tool (PART) process if the program is selected for PART review. Data will be collected from all 118 Healthy Marriage and 96 Responsible Fatherhood grantees in the OFA program. Grantees will report on program outputs and outcomes in such areas as participant's improvement in knowledge, skills, attitudes, and behaviors related to healthy marriage and responsible fatherhood. Grantees will be asked to input data for selected outputs and outcomes for activities funded under the grant. Grantees will extract data from program records and will report the data twice yearly through the ACF on-line data collection tool (OLDC). Training and assistance will be provided to grantees to support this data collection process.

Respondents: Office of Family Assistance Funded Healthy Marriage and Promoting Responsible Fatherhood Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Performance measure reporting form	214	2	0.80	342.40

Estimated Total Annual Burden Hours: 342.40.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: infocollection@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, Fax: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: December 22, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8-30833 Filed 12-24-08; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0637]

Agency Information Collection Activities; Proposed Collection; Comment Request; Financial Disclosure by Clinical Investigators

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, 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 information requiring the sponsor of any drug, biologic, or device marketing application to certify to the absence of clinical investigators and/or disclose those financial interests as required, when covered clinical studies are submitted to FDA in support of product marketing.

DATES: Submit written or electronic comments on the collection of information by February 27, 2009.

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: Elizabeth Berbakos, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3792.