

Under this SPA, the State indicated that it would provide for the implementation of an estate recovery program under sections 1902(a)(18) and 1917(b) of the Social Security Act (the Act). CMS issued a request for additional information on March 5, 2008, which included a request for information about the State's projected cost savings resulting from implementation of the estate recovery program. In discussions with CMS regarding submission of SPA 07-21, State officials stated that these projected cost savings estimates would require revision because the estate recovery program had in fact not yet become operational. The State did not provide additional information indicating when and to what extent it would come into compliance with sections 1902(a)(18) and 1917(b) of the Act. Thus, the State's overall submission did not provide sufficient detail or information for us to determine that the State has an estate recovery program that meets statutory requirements.

Based on the above, and after consultation with the Secretary of the Department of Health and Human Services as required under Federal regulations at 42 CFR 430.15(c)(2), CMS disapproved Michigan Medicaid SPA 07-21.

The hearing will involve the following issues:

- Whether the State complied with the statutory requirements to implement an estate recovery program; and
- Whether the State has provided the information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation.

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 Michigan announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Mr. Paul Reinhart, Director, Medical Services Administration, Department of Community Health, 400 South Pine, Lansing, MI 48933.

Dear Mr. Reinhart: I am responding to your request for reconsideration of the decision to disapprove the Michigan State plan amendment (SPA) 07-21, which was submitted on December 28, 2007, and disapproved on September 2, 2008.

Under this SPA, the State indicated that it would provide for the implementation of an estate recovery program under sections 1902(a)(18) and 1917(b) of the Social Security Act (the Act). The Centers for Medicare & Medicaid Services (CMS) issued a request for additional information on March 5, 2008, which included a request for information about the State's projected cost savings resulting from implementation of the estate recovery program. In discussions with CMS regarding submission of SPA 07-21, State officials stated that these projected cost savings estimates would require revision because the estate recovery program had in fact not yet become operational. The State did not provide additional information indicating when and to what extent it would come into compliance with sections 1902(a)(18) and 1917(b) of the Act. Thus, the State's overall submission did not provide sufficient detail or information for us to determine that the State has an estate recovery program that meets statutory requirements. Based on the above, and after consultation with the Secretary of the Department of Health and Human Services as required under Federal regulations at 42 CFR 430.15(c)(2), CMS disapproved Michigan Medicaid SPA 07-21.

The issues to be considered at the hearing are:

- Whether the State complied with the statutory requirements to implement an estate recovery program; and
- Whether the State has provided the information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation.

I am scheduling a hearing on your request for reconsideration to be held on January 6, 2009, at the CMS Chicago Regional Office,

233 N. Michigan Avenue, Suite 600, Chicago, Illinois 60601, in order to reconsider the decision to disapprove SPA 07-21. 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. section 1316; 42 CFR section 430.18)

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

Dated: November 7, 2008.

Kerry Weems,
Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Grants Awarded: Program Titles and Funding Opportunity Announcements for Fiscal Year 2009

AGENCY: Division of Grants Policy, Office of Financial Services, Office of Administration, Administration for Children and Families (ACF), Department of Health and Human Services (DHHS).

ACTION: Notice.

SUMMARY: The Administration for Children and Families (ACF) hereby gives notice to the public that certain programs within the Agency will administratively impose a matching requirement on grants awarded under the following program titles and funding opportunity announcements for Fiscal Year 2009:

Program office	Funding opportunity No.	Funding opportunity title	Fiscal year	Program title	CFDA No.	Administrative match percentage	Composition of the administrative attach
Administration for Children, Youth and Families—Children's Bureau.	HHS-2009-ACF-ACYF-CA-0055.	Rigorous Evaluations of Existing Child Abuse Prevention, Family Support, Family Preservation, Family Reunification, and Adoption Promotion and Support Programs.	2009	Community-Based Child Abuse Prevention Grants.	93.590	10	Cash and In-Kind.
Administration for Children, Youth and Families—Children's Bureau.	HHS-2009-ACF-ACYF-CB-0060.	Abandoned Infants Assistance Act: Comprehensive Support Services for Families Affected by Substance Abuse and/or HIV/AIDS.	2009	Abandoned Infants	93.551	10	Cash and In-Kind.
Administration on Developmental Disabilities.	HHS-2009-ACF-ADD-DN-0046.	Projects of National Significance: Family Support 360 Centers.	2009	Developmental Disabilities Projects of National Significance.	93.631	25	Cash and In-Kind.
Administration on Developmental Disabilities.	HHS-2009-ACF-ADD-DN-0047.	Projects of National Significance: Family Support 360 Special Initiatives.	2009	Developmental Disabilities Projects of National Significance.	93.631	25	Cash and In-Kind.
Administration on Developmental Disabilities.	HHS-2009-ACF-ADD-DN-0048.	Projects of National Significance: Family Support 360 for Military Families.	2009	Developmental Disabilities Projects of National Significance.	93.631	25	Cash and In-Kind.
Office of Community Services.	HHS-2009-ACF-OCS-EJ-0009.	Compassion Capital Fund Intermediary Demonstration Program.	2009	Compassion Capital Fund.	93.009	20	Cash and In-Kind.
Office of Child Support Enforcement.	HHS-2009-ACF-OCSE-FD-0013.	Section 1115 Demonstration 1.	2009	Child Support Enforcement Research.	93.564	5	Cash is preferred and In-Kind resources from public entities only are accepted.
Office of Child Support Enforcement.	HHS-2009-ACF-OCSE-FD-0017.	Section 1115 Demonstration 3.	2009	Child Support Enforcement Research.	93.564	5	Cash is preferred and In-Kind resources from public entities only are accepted.
Office of Child Support Enforcement.	HHS-2009-ACF-OCSE-FD-0019.	Section 1115 Demonstration 2.	2009	Child Support Enforcement Research.	93.564	5	Cash is preferred and In-Kind resources from public entities only are accepted.
Office of Child Support Enforcement.	HHS-2009-ACF-OCSE-FD-0052.	Section 1115 Demonstration 4.	2009	Child Support Enforcement Research.	93.564	5	Cash is preferred and In-Kind resources from public entities only are accepted.
Office of Planning, Research and Evaluation.	HHS-2009-ACF-OPRE-PD-0029.	TANF Research	2009	Social Services Research and Demonstration.	93.647	5	Cash and In-Kind.

Historically, ACF has found that the imposition of a matching requirement on awards under these programs results in an increased level of community

support and, often, a higher profile in the community. This can contribute to the success and sustainability of the project. The Fiscal Year 2009 funding

opportunity announcements for each listed program will advise applicants on the percentage of funds that must be contributed through non-Federal

resources, the composition of the match, and the merit of the match as a criterion in the competitive review. The administratively imposed matching requirement will apply only to new awards and their continuation awards, made under the Fiscal Year 2009 funding opportunity announcements listed in this notice. This Fiscal Year 2009 matching requirement does not represent an addition to the existing matching requirements on awards made under funding opportunity announcements issued in Fiscal Year 2008 or before. The amount and acceptable types of non-Federal resources allowed is not negotiable. However, matching may be provided as direct or indirect costs. The presence and composition of matching funds may be used as a criterion in evaluating the merits of an application during competitive review. Specific information related to the matching requirement and competitive review will be provided in each listed funding opportunity announcement. Unmatched Federal funds will be disallowed. Costs borne by matching contributions are subject to the regulations governing allowability found under 45 CFR 74.23 and 45 CFR 92.24.

The Department of Health and Human Services' Grants Forecast is a database of planned grant opportunities proposed by its various agencies. Each Forecast record contains actual or estimated dates and funding levels for grants that the agency intends to award during the fiscal year. Additional details about ACF planned FY2009 funding opportunity announcements can be found on the Grants Forecast Web site at <https://extranet.acf.hhs.gov/hhsgrantsforecast/>. Published ACF funding opportunity announcements are available on Grants.gov at <http://www.grants.gov> and the ACF Grant Opportunities Web page at <http://www.acf.hhs.gov/grants/open.html>.

FOR FURTHER INFORMATION CONTACT: Karen Shields, Grants Policy Specialist, Office of Administration, Division of Grants Policy, 370 L'Enfant Promenade, SW., 6th Floor East, Washington, DC 20447, or by telephone at 202-401-5112 or karen.shields@acf.hhs.gov.

Dated: November 5, 2008

Curtis L. Coy,

Deputy Assistant Secretary for Administration, Administration for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0556]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

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 the information collection contained in the guidance for industry on formal meetings with sponsors and applicants for Prescription Drug User Fee Act (PDUFA) products.

DATES: Submit written or electronic comments on the collection of information by January 12, 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.

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, including each proposed extension of an existing 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.

Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products (OMB Control Number 0910-0429)—Extension

This information collection approval request is for an FDA guidance on the procedures for formal meetings between FDA and sponsors or applicants regarding the development and review of PDUFA products. The guidance describes procedures for requesting, scheduling, conducting, and documenting such formal meetings. The guidance provides information on how the agency will interpret and apply section 119(a) of the Food and Drug Administration Modernization Act (the Modernization Act), specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82 (21 CFR 312.47 and 312.82)).

The guidance describes two collections of information: The submission of a meeting request containing certain information and the submission of an information package in advance of the formal meeting. Agency regulations at §§ 312.47(b)(1)(ii), (b)(1)(iv), and (b)(2) describe information that should be submitted in