

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
FAST-Levy Request Withhold Record Specifications: State Child Support Enforcement Agencies	7	1	317.5	2,222.5

Estimated Total Annual Burden Hours: 3,810.

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: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email 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, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.

[FR Doc. 2013-23884 Filed 9-30-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Final Notice To Announce the Implementation of Required Electronic Submission of State or Tribal Plans, and Program and Financial Reporting Forms for Mandatory Grant Programs

AGENCY: Office of Administration (OA), ACF, HHS.

ACTION: Final notice.

SUMMARY: The Administration for Children and Families (ACF), Office of Administration (OA) is issuing final notice of the implementation of required electronic submission of State or Tribal plans, and program and financial reporting forms for mandatory grant programs to ACF's Online Data

Collection system (OLDC). This notice includes responses to comments received under the initial notice published in the **Federal Register** (78 FR 38989-38891, June 28, 2013). Public comment on the proposed procedures closed on August 27, 2013.

This notice also corrects the absence in the June 28 notice of a reference that required electronic application submission also applies to Tribal plans and reporting.

DATES: Effective October 1, 2013.

FOR FURTHER INFORMATION CONTACT: Karen Shields, Grants Policy Specialist, Department of Health and Human Services, Administration for Children and Families, Division of Grants Policy, 370 L'Enfant Promenade SW., Aerospace Building, 6th Floor East, Washington, DC 20447. Email address: karen.shields@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: ACF has previously afforded recipients of mandatory grant programs the option of submitting State or Tribal plans, and programmatic and financial reporting forms, in both electronic and paper formats. On June 28, 2013, ACF announced that recipients of mandatory grant programs will be required to submit State plans, and programmatic and financial reporting forms electronically.

In response to the June notice, the ACF received several comments. The following information summarizes the comments received and the agency responses.

1. A commenter noted that all references to "State" should be changed to include plans and reporting submitted by Tribes, as well as those required of States, under mandatory grants.

We concur. ACF corrects and apologizes for the error in the original notice. All references to States in the earlier notice also apply to plans and reports required from Tribal grantees and applicants.

2. A commenter asked why required electronic submission would not include submission of reports under a discretionary grant program.

ACF responds that, at present, the requirement for electronic submission of reporting documents, implemented in this and the June 28 notices, applies

only to reporting by mandatory grant programs. An announcement concerning requirements for electronic reporting by grantees under discretionary grant programs will be made in the **Federal Register** in the future. Required electronic submission of applications to discretionary grant programs through www.Grants.gov was announced by ACF in **Federal Register** notice 76 FR 66721, October 27, 2011.

3. One commenter asked where applicants can obtain a copy of the SF-424M for use by State or Tribal plans, and another commenter requested specific instructions for use of the form.

The form is available on the Grants.gov Web site at: http://apply07.grants.gov/apply/forms/sample/SF424_Mandatory_1_2-V1.2.pdf. ACF Program Offices will provide detailed instructions to grantees and applicants affected by the change to required electronic submission.

4. Two commenters suggested that ACF continue to accept paper submissions of plans and reporting documents when natural disasters, disruptions of mail service, unscheduled electrical or system outages, or other rare events occur that would prevent electronic submission of the documents.

We respond that ACF has the authority to extend the filing deadline in these situations, upon request from the grantee. No exemption request from the electronic filing requirement is required under these circumstances. ACF will allow a paper submission via fax, or as an email attachment, in situations where the use of mail, courier, or overnight delivery service may not be sufficient to meet a specific deadline.

5. Other commenters requested clarification of the electronic submission requirement by asking whether attachments to plans must also be submitted electronically to ACF's OLDC system.

ACF responds that supplemental attachments and documentation to any State or Tribal plan, or to programmatic or financial reporting forms, may be uploaded electronically to OLDC.

6. Another commenter that had been submitting plans and reports in paper format asked if new users of the OLDC

system will be given credentials to use OLDC. Upon request, ACF will provide credentials and access to use the OLDC system to all applicants and grantees. Individuals already authorized to use OLDC may need their authorization updated to include additional programs or documents, if applicable. Affected ACF Program Offices will send detailed instructions to grantees and applicants.

7. The same commenter also asked whether submitted State Plans could be viewed by the public through ACF's OLDC system.

ACF responds that the OLDC system does not have the capability to allow viewing of submitted plans or reports by the public. ACF Program Offices that provide public viewing of submitted plans on their Web sites will continue that practice. States and Tribes should follow their internal procedures in making the determination to provide plans and reports for public viewing.

8. A commenter objected to the requirement by some ACF Program Offices that a paper copy of a submitted plan be distributed to the relevant ACF Regional Office. The same commenter also recommended that, once a plan is electronically signed and submitted to OLDC, ACF should not allow subsequent changes to the data unless the grantee is submitting a revised report, according to the reporting instructions.

ACF responds that, with the implementation of this requirement, once a grantee submits its plan or reporting forms into OLDC, the submission of a second paper copy is no longer required. ACF's Regional Office staff will access plans and reports using OLDC, eliminating the requirement for distribution of additional copies. And, we note that once a submission is signed and submitted in OLDC, any revisions, changes, or updates must be made by entering a revised report in OLDC. We note that there is no limit to the number of revised reports a grantee may submit; however, some date restrictions by the cognizant Program Office may apply to submission of revisions.

Statutory Authority: Financial Assistance Management Improvement Act of 1999, Pub. L. 106-107.

Robert Noonan,

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-2013-N-1163]

Agency Information Collection Activities: Proposed Collection; Comment Request; Institutional Review Boards

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 recordkeeping requirements for institutional review boards (IRBs).

DATES: Submit either electronic or written comments on the collection of information by December 2, 2013.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRASStaff@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,

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.

Institutional Review Boards—21 CFR Part 56.115 (OMB Control Number 0910-0130)—Extension

When reviewing clinical research studies regulated by FDA, IRBs are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: (1) Written procedures describing the structure and membership of the IRB and the methods that the IRB will use in performing its functions; (2) the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; (3) minutes of meetings showing attendance, votes and decisions made by the IRB, the number of votes on each decision for, against, and abstaining, the basis for requiring changes in or disapproving research; (4) records of continuing review activities; copies of all correspondence between investigators and the IRB; (5) statement of significant new findings provided to subjects of the research; and (6) a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by FDA in conducting audit inspections of IRBs to determine whether IRBs and clinical investigators are providing adequate protections to human subjects participating in clinical research.