

Information Collection: Post Clinical Laboratory Survey Questionnaire and Supporting Regulations in 42 CFR 493.1771, 493.1773, and 493.1777. *Use:* Form CMS-668B is used by a Clinical Laboratory Improvement Amendments (CLIA) laboratory to express its satisfaction with the survey process and to make recommendations for improvement. Surveyors furnish this form to all laboratories that receive either an onsite survey or the Alternate Quality Assessment Survey (i.e., paper survey of quality indicators). CMS Central Office performs an overview evaluation of the completed forms. Each calendar year, a summary of the information collected is sent to the State and CMS Regional Office. *Form Number:* CMS-668B (OCN 0938-0653). *Frequency:* Biennially; *Affected Public:* Business or other for-profits and not-for-profit institutions. State, Local, or Tribal Government, Federal Government. *Number of Respondents:* 21,000. *Total Annual Responses:* 10,500. *Total Annual Hours:* 2,625. (For policy questions regarding this collection contact Kathleen Todd at 410-786-3385. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: Extension of a currently approved collection. *Title of Information Collection:* Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations in 42 CFR 493.1-493.2001. *Use:* CMS 1557 is used to report surveyor findings during a CLIA survey. For each type of survey conducted (i.e., initial certification, recertification, validation, complaint, addition/deletion of specialty/subspecialty, transfusion fatality investigation, or revisit inspections) the Survey Report Form incorporates the requirements specified in the CLIA regulations. *Form Number:* CMS-1557 (OCN 0938-0544). *Frequency:* Biennially. *Affected Public:* Business or other for-profit, Not-for-profit institutions, State, Local or Tribal Governments and Federal Government. *Number of Respondents:* 21,000. *Total Annual Responses:* 10,500. *Total Annual Hours:* 5,248. (For policy questions regarding this collection contact Kathleen Todd at 410-786-3385. For all other issues call 410-786-1326.)

3. Type of Information Collection Request: New collection; *Title of Information Collection:* Analysis of Transportation Barriers to Utilization of

Medicare Services by American Indian and Alaska Native Medicare Beneficiaries; *Use:* The purpose of the proposed study is to identify and analyze transportation barriers associated with the utilization of Medicare services by American Indian and Alaska Native (AI/AN) beneficiaries, to identify and analyze the health outcomes resulting from those barriers, and ultimately to identify potential solutions that could help mitigate the problem and produce meaningful improvements in health care use and health outcomes for this population. Specifically, the information that will be collected through the use of instruments and the study developed under the Analysis of Transportation Barriers to Utilization of Medicare Services by American Indian and Alaska Native Medicare Beneficiaries Project has not been collected or evaluated previously by any agency or individual, so data on the extent of transportation barriers for rural AI/AN beneficiaries to Medicare services by AI/AN Medicare beneficiaries are not available except from the proposed data collection activity.

The information gathered as part of the project—through the use of survey, interview, and focus group instruments—will be used by CMS to identify transportation barriers to Medicare services for AI/AN Medicare beneficiaries. It will provide the first ever complete evaluation of transportation barriers to health care for this population.

The information collection request has been revised since the publication of the 60-day **Federal Register** notice. Several questions were added in response to public comments. In addition to new questions, several clarifying edits were made as well. *Form Number:* CMS-10399 (OMB # 0938-NEW); *Frequency:* Occasionally; *Affected Public:* Individuals and Households, Private Sector; *Number of Respondents:* 3,418; *Total Annual Responses:* 3,418; *Total Annual Hours:* 2,544. (For policy questions regarding this collection contact Roger Goodacre at 410-786-3209. 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 May 18, 2012.

OMB, Office of Information and Regulatory Affairs,
Attention: CMS Desk Officer,
Fax Number: (202) 395-6974,
Email: OIRA_submission@omb.eop.gov.

Dated: April 12, 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

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: National Youth in Transition Database and Youth Outcome Survey.

OMB No.: 0970-0340.

Description: The Foster Care Independence Act of 1999 (42 U.S.C. 1305 *et seq.*) as amended by Public Law 106-169 requires State child welfare agencies to collect and report to the Administration on Children and Families (ACF) data on the characteristics of youth receiving independent living services and information regarding their outcomes. The regulation implementing the National Youth in Transition Database, listed in 45 CFR 1356.80, contains standard data collection and reporting requirements for States to meet the law's requirements. ACF will use the information collected under the regulation to track independent living services, assess the collective outcomes of youth, and potentially to evaluate State performance with regard to those outcomes consistent with the law's mandate.

Respondents: State agencies that administer the John H. Chafee Foster Care Independence Program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Youth Outcome Survey	15,334	1	0.50	7,667
Data File	52	2	1,201	124,904

Estimated Total Annual Burden Hours: 132,571.

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 Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012-9337 Filed 4-17-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0324]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry, FDA Staff, and Foreign Governments: Fiscal Year 2012 Medical Device User Fee Small Business Qualification and Certification

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 Form FDA 3602 and Form FDA 3602A, which will allow domestic and foreign applicants to certify that they qualify as a "small business" and pay certain medical device user fees at reduced rates.

DATES: Submit either electronic or written comments on the collection of information by June 18, 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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-

400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@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.

Guidance for Industry, FDA Staff, and Foreign Governments: Fiscal Year 2012 Medical Device User Fee Small Business Qualification and Certification—(OMB Control Number 0910-0508)—Extension

Section 101 of the Medical Device User Fee and Modernization Act (MDUFMA) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to provide for user fees for certain medical device applications. FDA