

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; *Title:* Medicare Advantage Quality Bonus Payment Demonstration; *Use:* In response to the provision of the Affordable Care Act, beginning in 2012, quality bonus payments (QBP) are given to all plans earning four or five stars in Medicare's Star Rating program. As an extension of this legislation, CMS launched the Medicare Advantage Quality Bonus Payment Demonstration, which accelerates the phase-in of QBP by extending bonus payments to three-star plans and eliminating the cap on blended county benchmarks that would otherwise limit QBP. Through this demonstration, CMS seeks to understand how incentive payments impact plan quality across a broader spectrum of plans.

The data collection effort will be conducted in the form of a survey of Medicare Advantage Organizations (MAOs) and up to 10 case studies with MAOs in order to supplement what can be learned from the analyses of administrative and financial data for MAOs, and from an environmental and literature scan. The data collected is needed to evaluate the QBP demonstration to better understand what impact the demonstration has had on MAO operations and their efforts to improve quality. The data collection instrument is a survey questionnaire designed to capture information on how MAOs perceive the demonstration and are planning for or implementing changes in quality initiatives and to identify factors that help or hinder the capacity to achieve quality improvement and that influence the

decision calculus to make changes. Specifically, the information is expected to provide a detailed picture to CMS of the kinds of quality initiatives utilized by MAOs and some preliminary information on how they assess the effectiveness of these programs. The survey is designed to provide an overall picture of the QBP that can be used for national comparisons across plans as part of the larger evaluation of the QBP demonstration.

The case studies will be conducted as a series of open-ended discussions with MAO staff that will be guided by a discussion protocol. The case studies will supplement the information gathered from the survey and data analysis, providing valuable context and details about successful quality improvement activities. The case studies are particularly well suited to exploring the detailed characteristics of the plans' quality improvement activities, emphasizing the decision-making and thought processes underlying the structure and direction of their efforts and capturing the contextual factors that impact the nature, structure, and scope of the programs. The 60-day **Federal Register** notice published on September 17, 2012, (77 FR 57090). Subsequently, there were revisions to the MAO survey. *Form Number:* CMS-10445 (OCN: 0938-New); *Frequency:* Annual; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 730; *Total Annual Responses:* 1,280; *Total Annual Hours:* 683. (For policy questions regarding this collection contact Gerald Riley at 410-786-6699. 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](mailto: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 *March 27, 2013*.

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

Dated: February 19, 2013.

**Martique Jones,**

*Deputy Director, Regulations Development Group, 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:* Annual Survey of Refugees (Form ORR-9).

*OMB No.:* 0970-0033.

*Description:* The Annual Survey of Refugees collects information on the social and economic characteristics of a random sample of refugees, Amerasians, and entrants who arrived in the United States in the five years prior to the date of the survey. The survey focuses on employment and other training, labor force participation, and welfare utilization rates. From the responses, the Office of Refugee Resettlement reports on the economic adjustment of refugees to the American economy. These data are used by Congress in its annual deliberations on refugee admissions and funding and by program managers in formulating policies for the future direction of the Refugee Resettlement Program.

*Respondents:* Refugees, Amerasians, and entrants.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR-9 Annual Survey of Refugees .....	2,000	1	0.62	1,240
Request for Participation Letter .....	2,000	1	0.05	100

Estimated Total Annual Burden Hours: 1,340

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](mailto: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.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* State Self-Assessment Review and Report.

OMB No.: 0970-0223.

*Description:* Section 454(15)(A) of the Social Security Act, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, requires each State to annually assess the performance of its child support enforcement program in accordance with standards specified by the Secretary of the Department of Health and Human Services, and to provide a report of the findings to the Secretary. This information is required to determine if States are complying with Federal child support mandates and providing the best services possible. The report is also intended to be used as a management tool to help States evaluate their programs and assess performance.

*Respondents:* State Child Support Enforcement Agencies or the Department/Agency/Bureau responsible for Child Support Enforcement in each State.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Self-assessment report .....	54	1	4	216

Estimated Total Annual Burden Hours: 216.

*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](mailto: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: 202-395-7285, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the

Administration for Children and Families.

**Robert Sargis,**  
*Reports Clearance Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2005-D-0282; formerly 2005D-0183]

**Draft Guidance for Industry on Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting Hepatitis C Virus Resistance Data; Availability**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the

Agency: Guidance for Submitting HCV Resistance Data." The purpose of this attachment is to assist sponsors in submitting hepatitis C virus (HCV) clinical virology data, which are important for supporting clinical trials of products in development for the treatment of HCV. HCV resistance data submitted in appropriately formatted datasets is a critical component in the review of investigational antiviral products for the treatment of HCV. The information in this attachment will facilitate the development and regulatory review of anti-HCV products.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 26, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY**