

the minimization of burden (including the use of information technology).

Comments received in response to this notice will be summarized for, and may be included with, the OGE request for extension of the OMB paperwork approval for the set of the various existing qualified trust model certificates, the model communications package, and the model trust documents. The comments will also become a matter of public record.

Approved: December 22, 2004.

Marilyn L. Glynn,

Acting Director, Office of Government Ethics.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-209 and CMS-10008]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (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:* Extension of a currently approved collection; *Title of Information Collection:* Laboratory Personnel Report (Clinical Laboratory Improvement Amendments of 1988 (CLIA)) and Supporting Regulations in 42 CFR 493.1357, 493.1363, 493.1405, 493.1406, 493.1411, 493.1417, 493.1423, 493.1443, 493.1449, 493.1455, 493.1461, 493.1462, 493.1469, 493.1483, 493.1489, and 493.1491; *Use:* This form is used by

the State agency to determine a laboratory's compliance with personnel qualifications under CLIA. This information is needed for a laboratory's certification and recertification; *Form Number:* CMS-209 (OMB#: 0938-0151); *Frequency:* Biennially; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 21,000; *Total Annual Responses:* 10,500; *Total Annual Hours:* 5,250.

2. *Type of Information Collection:* Revision of a currently approved collection; *Title of Information Collection:* Process and Information Required to Determine Eligibility of Drugs, Biologicals, and Radio-pharmaceutical Agents for Transitional Pass-Through Provisions Under the Hospital Outpatient Prospective Payment System (OPPS) and Supporting Regulations in 42 CFR, Section 419.43; *Use:* Section 1833(t)(6) of the Social Security Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biological agents. Interested parties such as hospitals, pharmaceutical companies, and physicians can apply for transitional pass-through payment for drugs and biologicals used with services covered under the OPPS. CMS uses this information to determine if the criteria for making a transitional pass-through payment are met and if an interim HCPCS code for a new drug or biological is necessary. The revisions made to this collection include the addition of Section 303 of the MMA. This new section establishes the use of the average sales price (ASP) methodology for payments; *Form Number:* CMS-1008 (OMB# 0938-0802); *Frequency:* On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 58; *Total Annual Responses:* 58; *Total Annual Hours:* 203.

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/regulations/pira/>, or E-mail 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.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Reduction Act Reports Clearance Officer designated at

the address below: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Melissa Musotto, Room C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 29, 2004.

John P. Burke, III,

CMS Paperwork Reduction Act Reports Clearance Officer, Officer of Strategic Operations and Regulatory Affairs, Regulations Development Group.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-268]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Survey Tool for Medicare.gov Web site; *Form No.:* CMS-R-268 (OMB# 0938-0756); *Use:* CMS developed a survey tool using MSInteractive to obtain feedback from users accessing medicare.gov Web site to guide future improvements. The Web site was produced in concert with the administration's goal of providing better customer service to all our constituents. The underlying principle of the site is to have a single modified Internet