

PRA submission combines OMB approval for PACE, WPP 0938-0844 with OMB approval for MSHO/MnDHO 0938-0899 and requests to administer the PHS to beneficiaries enrolled in MassHealth SCO as well as administer the PHS in year 2005. The main purpose of the PHS is to collect health status information that may be used to adjust Medicare payment to MSHO/MnDHO health plan organizations. It has been successfully pilot-tested to assess response rates and accuracy of responses under different distribution approaches. The pilot test enabled CMS to select an approach whereby PACE and Dual Eligible Demonstration enrollees will be sent surveys to fill out and can request assistance from family or professionals; *Frequency*: Annually; *Affected Public*: Individuals or Households and Not-for-profit institutions; *Number of Respondents*: 15,859; *Total Annual Responses*: 10,785; *Total Annual Hours*: 1,798.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at <http://cms.hhs.gov/regulations/prs/default.asp>, 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 Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willingham, Room: C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: July 10, 2003.

Dawn Willingham,

CMS Reports Clearance Officer, Division of Regulations Development and Issuances, Office of Strategic Operations and Strategic Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-588, CMS-1514, CMS-368/R-144]

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

AGENCY: Centers for Medicare and 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 and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (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 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:* Revision of a currently Approved collection; *Title of Information Collection:* Authorization agreement for electronic forms transfer; *Form No.:* CMS-0588 (OMB# 0938-0626); *Use:* The information is needed to allow providers to receive funds electronically in their bank accounts; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 10,000; *Total Annual Responses:* 10,000; *Total Annual Hours:* 1,250.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospital Request for Certification in the Medicare/Medicaid Program; *Form No.:* CMS-1514 (OMB# 0938-0380); *Use:* Section 1861 of the Social Security Act requires hospitals and critical access hospitals to be certified to participate in the Medicare/Medicaid program. These providers must complete the "Hospital Request for Certification in the Medicare/Medicaid Program" form in

order to be certified or recertified; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 6,300; *Total Annual Responses:* 2,000; *Total Annual Hours:* 500.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate; *Form No.:* 0938-0582; *Use:* Section 1927 requires State Medicaid agencies to report to drug manufacturers and CMS on the drug utilization for their State and the amount of rebate to be paid by the manufacturer; *Frequency:* Quarterly; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 51; *Total Annual Responses:* 204; *Total Annual Hours:* 6,125.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at <http://cms.hhs.gov/regulations/prs/default.asp>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to paperwork@hcfpa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 10, 2003.

Dawn Willingham,

Acting Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D-0195]

Guidance for Industry on Necessity of the Use of Food Product Categories in Registration of Food Facilities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.