

Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Melissa Musotto, Room C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: October 30, 2003.

**Julie Brown,**

*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**

**Centers for Medicare and Medicaid Services**

[Document Identifier: CMS-576, CMS-3427, CMS-R-282, CMS-372S]

**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 (HCFA), 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:* Extension of a currently approved collection;

*Title of Information Collection:* Organ Procurement Organization (OPO) Request for Designation and Supporting Regulations in 42 CFR 486.304, 486.306, and 486.307; *Form No.:* CMS-576 (OMB# 0938-0512); *Use:* The information provided on this form serves as a basis for certifying OPOs for participation in the Medicare and Medicaid programs and will indicate

whether the OPO is meeting the specified performance standards for reimbursement of service; *Frequency:* Annually; *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 59; *Total Annual Responses:* 59; *Total Annual Hours:* 118.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Application and Survey and Certification Report and Supporting Regulations in 42 CFR 488.60; *Form No.:* CMS-3427 (OMB# 0938-0360); *Use:* Part I of this form is a facility identification and screening measurement used to initiate the certification and recertification of ESRD facilities. Part II is completed by the Medicare/Medicaid State survey agency to determine facility compliance with ESRD conditions for coverage; *Frequency:* Every three years; *Affected Public:* Business or other for-profit institutions, Not-for-profit institutions; *Number of Respondents:* 4000; *Total Annual Responses:* 1,320; *Total Annual Hours:* 440.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare + Choice (M+C) Organization Appeals and Grievance Data Disclosure Requirements and Supporting Regulations in 42 CFR 422.64, 422.111, and 422.560-422.626; *Form No.:* CMS-R-282 (OMB# 0938-0778); *Use:* M+C organizations will collect information on appeals and grievance dispositions to help CMS monitor plan performance and to provide information to beneficiaries to help them make informed decisions about their or potential health plans' performance; *Frequency:* Semi-Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 211 *Total Annual Responses:* 422 *Total Annual Hours:* 422.

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Report on Home and Community Based Services Waivers and Supporting Regulations in 42 CFR 440.180 and 441.300-310; *Form No.:* CMS-372(S) (OMB# 0938-0272); *Use:* States request waivers in order for beneficiaries to have the option of receiving hospital services in their homes. States with an approved waiver under section 1915(c) of the Act are required to submit the CMS-372(S) annually in order for CMS to: (1) Verify that State assurances regarding waiver cost-neutrality are met,

and (2) determine the waiver's impact on the type, amount and cost of services provided under the State plan and health and welfare of recipients; *Frequency:* Annually; *Affected Public:* State, local or tribal government; *Number of Respondents:* 50; *Total Annual Responses:* 277; *Total Annual Hours:* 20,775.

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://cms.hhs.gov/regulations/pr/default.asp>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.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: October 30, 2003.

**Julie Brown,**

*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. 2003N-0482]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Facilities, Standards, and Lay Summaries for Patients**

**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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on