

description of the reconsideration and appeals processes. These notices fulfill the statutory requirement.; *Frequency*: On occasion and other: distribution; *Affected Public*: Individuals or households, business or other for-profit, not-for-profit institutions; *Number of Respondents*: 211; *Total Annual Responses*: 71,200; *Total Annual Hours*: 7,120.

**2. Type of Information Collection**  
*Request*: Revision of a currently approved collection; *Title of Information Collection*: End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration and Supporting Regulations in 42 CFR 405.2133; *Form No.*: CMS-2728 (OMB# 0938-0046); *Use*: This form captures the necessary medical information required to determine Medicare eligibility of an end stage renal disease claimant. It also captures the specific medical data required for research and policy decisions on this population as required by law.; *Frequency*: weekly, monthly, quarterly, semi-annually and annually; *Affected Public*: Individuals or households, business or other for-profit, not-for-profit institutions; *Number of Respondents*: 100,000; *Total Annual Responses*: 100,000; *Total Annual Hours*: 75,000.

**3. Type of Information Collection**  
*Request*: Extension of a currently approved collection; *Title of Information Collection*: Home health Medicare Conditions of Participation (CoP) Information Collection Requirements and Supporting Regulations in 42 CFR 484.10, 484.12, 484.14, 484.16, 484.18, 484.36, 484.48, and 484.52; *Form No.*: CMS-R-39 (OMB# 0938-0365); *Use*: 42 CFR part 484 outlines Home Health Agency Medicare CoP to ensure HHAs meet the Federal patient health and safety regulations; *Frequency*: Annually; *Affected Public*: Business or other for-profit, not-for-profit institutions, Federal government, and State, local or tribal government; *Number of Respondents*: 7,422; *Total Annual Responses*: 7,422; *Total Annual Hours*: 854,891.

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; Fax (202)395-6929.

Dated: March 4, 2004.

**John P. Burke, III,**

*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

### Centers for Medicare and Medicaid Services

[Document Identifier: CMS-R-297]

#### Agency Information Collection Activities: Proposed Collection; 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.

*Type of Information Collection*  
*Request*: Extension of a currently approved collection; *Title of Information Collection*: Request for Employment Information; *Form No.*: CMS-R-297 (OMB# 0938-0787); *Use*: This information is needed to determine whether a beneficiary can enroll in part B under section 1837(i) of the Act and/or qualify for a reduction in the premium amount under section 1839(b) of the Act.; *Frequency*: On occasion; *Affected Public*: Business or

other for-profit; *Number of Respondents*: 5000; *Total Annual Responses*: 5000; *Total Annual Hours*: 750.

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/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 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: Melissa Musotto, Room C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: March 4, 2004.

**John P. Burke III,**

*Paperwork Reduction Act Team Leader, 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

#### Industry Exchange Workshop on FDA Clinical Trial Requirements; Public Workshop

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Detroit District, in cooperation with the Society of Clinical Research Associates, (SoCRA) is announcing a workshop on FDA clinical trial statutory and regulatory requirements. Topics for discussion include: Pre-IND (investigational new drug application) meetings and FDA meeting process, medical device, drug and biological product aspects of clinical research, investigator initiated research, informed consent requirements, adverse event reporting, how FDA conducts bioresearch inspections, ethics in subject enrollment, FDA regulation of Institutional Review Boards, FDA and