

identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 31, 1997.

**Joseph A. Levitt,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 97-32968 Filed 12-17-97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-265]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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 the 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:* Reinstatement without change of a previously approved collection for which approval has expired; *Title of Information Collection:* Independent Renal Dialysis Facility Cost Report Form and Supporting Regulations 42 CFR 413.198, 413.20; *Form No.:* HCFA-265; *Use:* The Medicare Independent Renal Dialysis Facility Cost Report provides for determinations and allocation of costs to the components of the Renal

Dialysis facility in order to establish a proper basis for Medicare payment. *Frequency:* Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 2,472; *Total Annual Responses:* 2,472; *Total Annual Hours:* 484,512.

*2. Type of Information Collection Request:* New Collection; *Title of Information Collection:* Evaluation of the Oregon Medicaid Reform Demonstration: Phase II Adult Interview, Phase II Child Interview, Survey of Agency Providers; *Form No.:* HCFA-R-221; *Use:* These survey instruments will be used to evaluate the Oregon Medicaid Reform Demonstration. The Phase II Adult and Phase II Child interviews are designed to collect information on health status, access to care and past health insurance status for adults and children participating in Phase II of the Oregon Health Plan (OHP). The survey of Agency providers is designed to collect information on the experience under OHP of agencies that traditionally treat disabled and elderly Medicaid beneficiaries. *Frequency:* One Time; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Governments; *Number of Respondents:* 4,150; *Total Annual Responses:* 4,150; *Total Annual Hours:* 1,730.

*3. Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Health Maintenance Organizations & Competitive Medical Plans National Data Reporting Requirements and Supporting Regulations 42 CFR 417.100, .940, .126, .478, .162; *Form No.:* HCFA-906; *Use:* This form captures information which governs qualification of new Health Maintenance Organizations (HMOs) and the eligibility of Competitive Medical Plans (CMPs), employer compliance, recovery of Federal loan and loan guarantees, financial disclosure, and continuing regulation of qualified HMOs and CMPs which provide health care services to beneficiaries for a fixed fee which is paid on a periodic basis. *Frequency:* Other; Annually, Quarterly; *Affected Public:* Federal Government, Business or other for-profit, Not-for-profit institutions, State, local or Tribal Government; *Number of Respondents:* 313; *Total Annual Responses:* 953; *Total Annual Hours:* 3,130.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or any related forms, E-mail your request,

including your address and phone number, to 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 HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 11, 1997.

**John P. Burke III,**

*HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

Document Identifier: HCFA-179

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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:* Revision of a currently approved collection; *Title of Information Collection:* Transmittal and Notice of Approval of State Plan Material and Supporting Regulations in 42 CFR 430.10-430.20 and 440.167; *Form No.:* HCFA-179 (OMB #0938-