

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.

[FR Doc. 97-33064 Filed 12-17-97; 8:45 am]

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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-

0193); *Use*: The HCFA-179 is used by State agencies to transmit State plan material to HCFA for approval prior to amending their State plan. The State Plan is the method in which States inform staff of State policies, standards, procedures and instructions; *Frequency*: On occasion; *Affected Public*: State, local and tribal government; *Number of Respondents*: 57; *Total Annual Responses*: 1,254; *Total Annual Hours*: 1,254.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, 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: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 12, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 97-33067 Filed 12-17-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-53]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

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: Extension of a currently approved collection; *Title of Information Collection:* Imposition of Cost Sharing Charges Under Medicaid and Supporting Regulations contained in 42 CFR 447.53; *Form No.:* HCFA-R-53 (OMB# 0938-0429); *Use:* The information collection requirements contained in 42 CFR 447.53 require the States to include in their Medicaid State Plan their cost sharing provisions for the medically and categorically needy. The State Plan is the method in which States inform staff of State policies, standards, procedures and instructions; *Frequency:* Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 54; *Total Annual Responses:* 54; *Total Annual Hours:* 2,700.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, 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: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 10, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 97-33071 Filed 12-17-97; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Form #HCFA-855]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 (DHSS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 C.F.R., Part 1320. The Agency cannot reasonably comply with the normal clearance procedures because a statutory deadline imposed by the Balanced Budget Act of 1997 (Pub. L. 105-33). Without this information, HCFA would not be able to properly implement the requirements set forth in the statute.

HCFA is requesting OMB review and approval of this collection by 12/31/97, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individual designated below, by 12/29/97.

During this 180-day period HCFA will pursue OMB clearance of this collection as stipulated by 5 CFR. 1320.5.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare and Other Federal Health Care Program Providers/Supplier Enrollment Application; *Form No.:* HCFA-855, HCFA-855C, HCFA-855R, HCFA-855S; *Use:* This information is needed to enroll providers and suppliers into the Medicare program by identifying them, and verifying their qualifications and eligibility to participate in Medicare, and to price and pay their claims.; *Frequency:* Initial Enrollment/Recertification; *Affected Public:* Business or other for-profit, individuals or households, not-for-profit institutions, and Federal Government; *Number of Respondents:* 225,000; *Total Annual Responses:* 225,000; *Total Annual Hours:* 435,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web