

amendments no later than August 18, 1998, which is 180 days from the effective date of FDAMA. For full or abbreviated applications approved between February 19, 1998, and August 18, 1998, manufacturers, packers, and distributors have until August 18, 1998, to comply with the amendments. The guidance also advises that full or abbreviated applications submitted after February 19, 1998, should provide labels in compliance with the amendments.

This guidance document represents the agency's current thinking on implementation of elimination of certain labeling requirements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 3, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-6572 Filed 3-13-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-417 and HCFA-724]

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.

1. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Hospice Request for Certification in the Medicare Program; **Form No.:** HCFA-417 (OMB# 0938-0313); **Use:** The Hospice Request for Certification Form is used for hospice identification, screening, and to initiate the certification process. The information captured on this form is entered into a data base which assists HCFA in determining whether providers have sufficient personnel to participate in the Medicare program. The form summarizes data relative to: type of hospice; types of services provided by the hospice; and number of full time equivalents; **Frequency:** Annually; **Affected Public:** Business or other for-profit, Not-for-profit institutions, Federal Government, and State, local or tribal government; **Number of Respondents:** 2,286; **Total Annual Responses:** 2,286; **Total Annual Hours:** 572.

2. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Medicare/Medicaid Psychiatric Hospital Survey Data and Supporting Regulations Contained in 42 CFR 482.60, 482.61 and 482.62; **Form No.:** HCFA-724 (OMB# 0938-0378); **Use:** The Medicare/Medicaid Psychiatric Hospital Survey Data Form is used for hospital identification, and program planning and evaluation. The information captured on this form is entered into a data base which assists HCFA in maintaining accurate information on all free-standing psychiatric hospitals participating in the Medicare program. The form summarizes data relative to: hospital characteristics; types of services provided by the hospital; and hospital statistics; **Frequency:** Annually; **Affected Public:** Federal government, Business or other for-profit, Not-for-profit institutions, and State, local or tribal government; **Number of Respondents:** 350; **Total Annual Responses:** 350; **Total Annual Hours:** 175.

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: March 5, 1998.

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. 98-6453 Filed 3-12-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-26]

Agency Information Collection Activities: Submission for OMB Review; 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:* Clinical Laboratory Improvement Amendment (CLIA) and the Information Collection Requirements (ICRs) contained in the Supporting Regulations 42 CFR 493.1–2001; *Form No.:* HCFA–R–26 (OMB# 0938–0612); *Use:* The ICRs referenced in 42 CFR 493.1–2001 outline the requirements necessary to determine an entities compliance with CLIA. CLIA requires laboratories that perform testing on human specimens to meet performance requirements in order to be certified by HHS. HHS conducts inspections in order to determine a laboratory's compliance with the CLIA requirements. CLIA implements certificate, laboratory standards and inspection requirements; *Frequency:* As needed; *Affected Public:* Individuals or Households, Business or other for profit, Not for profit institutions, Federal Government, State, local or tribal government; *Number of Respondents:* 149,700; *Total Annual Responses:* 631,459; *Total Annual Hours:* 9,133,625.

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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: March 2, 1998.

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. 98–6438 Filed 3–12–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–906]

Agency Information Collection Activities: Submission for OMB Review; 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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. 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:* 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:* 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, 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 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: March 4, 1998.

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. 98–6448 Filed 3–12–98; 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: Submission for OMB Review; 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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. 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.