effective treatments. The design of clinical programs for developing drugs, devices, or biological products intended for the treatment of OA was the subject of a previous draft guidance issued in February 1998 (63 FR 8208, February 18, 1998). The February 1998 draft guidance generated several comments and was the subject of discussion at the Arthritis Advisory Committee meeting held on February 20, 1998.

The agency found the comments and the discussion at the advisory committee meeting very helpful in developing the recommendations to industry, contained in the guidance, on the design of clinical programs for developing drugs, devices, or biological products intended for the treatment of OA. However, the agency believes that more public input would be beneficial in preparing a final version of the guidance. Accordingly, the agency has decided to issue this revised version of the guidance as a draft.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on developing drugs, devices, or biological products intended for the treatment of OA. 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 requirements of the applicable statute, regulations, or both.

Interested persons may, on or before September 13, 1999, submit to the Dockets Management Branch (address above) written comments on the draft document. 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 draft document, appended questions, and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–18031 Filed 7–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–9042]

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: Request for Accelerated Payments and Supporting Regulations in 42 CFR 412.116 and 413.64;

Form No.: HCFA–9042;

Use: Medicare reimbursements are usually arranged through a fiscal intermediary who serves as the Secretary's agent for reviewing claims and making payments equal to the provider's reasonable costs. When a delay in Medicare payment by a fiscal intermediary, for covered services, causes financial difficulties for a provider, the provider may request an accelerated payment. An accelerated payment may also be made in highly exceptional situations where a provider has incurred a temporary delay in its bill processing beyond the provider's normal billing cycle. An accelerated payment can be requested by a provider that is not receiving periodic interim payments. These forms are used by fiscal intermediaries to access a provider's eligibility for accelerated payments.

Frequency: On occasion;

Affected Public: Business or other for-profit, and Not for-profit institutions;

Number of Respondents: 890;

Total Annual Responses: 890;

Total Annual Hours Requested: 445.

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, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 16, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–18007 Filed 7–14–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–0209 and HCFA–1557]

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:* Laboratory Personnel Report Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations in 42 CFR 493.1–493.2001; *Form No.:* HCFA–0209 (OMB #0938–0151); *Use:* CLIA requires the Department of Health and Human Services (DHHS) to establish certification requirements for any laboratory that performs tests on human specimens, and to certify through the issuance of a certificate that those laboratories meet the requirements established by DHHS. The information collected on this survey form is used in the administrative pursuit of the Congressionally-mandated program with regard to regulation of laboratories participating in CLIA. Information on personnel qualifications of all technical personnel is needed to ensure the sample is representative of all laboratories; *Frequency:* Biennially; *Affected Public:* Business or other for profit, Not for profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 26,500; *Total Annual Responses:* 13,250; *Total Annual Hours:* 6,625.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Survey Report Form Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations in 42 CFR 493.1–493.2001; *Form No.:* HCFA–1557 (OMB #0938–0544); *Use:* CLIA requires the Department of Health and Human Services (DHHS) to establish certification requirements for any laboratory that performs tests on human specimens, and to certify through the issuance of a certificate that those laboratories meet the requirements established by DHHS. The information collected on this survey form is used in the administrative pursuit of the Congressionally-mandated program with regard to regulation of laboratories participating in CLIA. In order for the State survey agency to report to HCFA its findings on facility compliance with the individual standards on which HCFA determines compliance, the surveyor completes the Survey Report Form. The Survey Worksheet provides space to document the surveyor's notes; *Frequency:* Biennially; *Affected Public:* Business or other for profit, Not for profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 30,512; *Total Annual Responses:* 15,526; *Total Annual Hours:* 7,628.

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, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Louis Blank, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 8, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–18079 Filed 7–14–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–484]

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: Extension of a currently approved collection;

Title of Information Collection: Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Regulations in 42 CFR 410.38 and 424.5;

Form No.: HCFA–484 (OMB# 0938–0534);

Use: To determine if oxygen is reasonable and necessary pursuant to Medicare Statute, Medicare claims for home oxygen therapy must be supported by the treating physician's statement and other information including estimate length of need (# of months), diagnosis codes (ICD–9) and:

1. Results and date of the most recent arterial blood gas PO^2 and/or oxygen saturation tests.

2. The most recent arterial blood gas PO^2 and/or oxygen saturation test performed EITHER with the patient in a chronic stable state as an outpatient, OR within two days prior to discharge from an inpatient facility to home.

3. The most recent arterial blood gas PO^2 and/or oxygen saturation test performed at rest, during exercise, or during sleep.

4. Name and address of the physician/provider performing the most recent arterial blood gas PO^2 and/or oxygen saturation test.

5. If ordering portable oxygen, information regarding the patient's mobility within the home.

6. Identification of the highest oxygen flow rate (in liters per minute) prescribed.

7. If the prescribed liters per minute (LPM), as identified in item 6, are greater than 4 LPM, provide the results and date of the most recent arterial blood gas PO^2 and/or oxygen saturation test taken on 4 LPM.

If the PO^2 = 56–59, or the oxygen saturation = 89%, then evidence of the beneficiary meeting at least one of the following criteria must be provided.

8. The patient having dependent edema due to congestive heart failure.

9. The patient having cor pulmonale or pulmonary hypertension, as documented by pulmonale on an EKG or by an echocardiogram, gated blood pool scan or direct pulmonary artery pressure measurement.

10. The patient having a hematocrit greater than 56%.

Form HCFA–484 obtains all pertinent information and promotes national consistency in coverage determinations.;

Frequency: Other (as needed);

Affected Public: Business or other for-profit, and Federal Government;