

however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal

Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: April 15, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97-10339 Filed 4-21-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Form # HCFA-484; OMB # 0938-0534]

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 (DHHS), 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 CFR Part 1320 and public harm is likely to occur. The Oxygen Certificate of Medical Necessity, completed by a Medicare beneficiary's treating physician and a durable medical equipment supplier, must be submitted to the appropriate Medicare Durable Medical Equipment Regional Carrier before a Medicare beneficiary is deemed eligible for home oxygen therapy and before a durable medical equipment supplier is eligible for reimbursement. If emergency clearance is not provided, beneficiaries may be provided vital health services in an untimely manner or may be required to pay for oxygen services normally paid for by the Federal government.

HCFA is requesting that after the 30-day comment period has concluded, OMB complete its review within 7-days and provide a 180-day approval. During this 180-day period HCFA will publish a separate **Federal Register** notice announcing the initiation of a 60-day agency review and public comment period on these requirements. Then HCFA will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Request: Reinstatement of a collection with a change of a previously approved collection for which approval has

expired (OMB approval # 0938-0534); *Title of Information Collection:*

Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Regulations 42 CFR 410.38 and 42 CFR 424.5; *Form Number:* HCFA-484; *Use:* To determine 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 PO₂ and/or oxygen saturation tests.

2. The most recent arterial blood gas PO₂ 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 PO₂ 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 PO₂ 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 PO₂ and/or oxygen saturation test taken on 4 LPM.

If the PO₂=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 P 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:* Individuals /households, business or other for profit, and not for profit institutions; *Number of Respondents:* 300,000; *Total Annual Responses:* 300,000; *Total Annual Hours Requested:* 50,000.

BILLING CODE 4120-03-P

FORM APPROVED
OMB NO. 0938-0534

OXYGEN

SECTION A		Certification Type/Date: INITIAL <u> </u> / <u> </u> / <u> </u> REVISED <u> </u> / <u> </u> / <u> </u> RECERTIFICATION <u> </u> / <u> </u> / <u> </u>	
PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER <div style="margin-top: 20px;">() - - - - - HICN</div>		SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER <div style="margin-top: 20px;">() - - - - - NSC #</div>	
PLACE OF SERVICE	HCPCS CODE	PT DOB <u> </u> / <u> </u> / <u> </u> ; Sex <u> </u> (M/F); HT. <u> </u> (In.); WT. <u> </u> (lbs.)	
NAME and ADDRESS of FACILITY if applicable (See Reverse)	<div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div>	PHYSICIAN NAME, ADDRESS, TELEPHONE and UPIN NUMBER <div style="margin-top: 20px;">() - - - - - UPIN #</div>	
SECTION B Information in This Section May Not Be Completed by the Supplier of the Items/Supplies.			
EST. LENGTH OF NEED (# OF MONTHS): <u> </u> 1-99 (99=LIFETIME)		DIAGNOSIS CODES (ICD-9): <u> </u>	
ANSWERS	ANSWER QUESTIONS 1-10. (Circle Y for Yes, N for No, or D for Does Not Apply, unless otherwise noted.)		
a) <u> </u> mm Hg b) <u> </u> % c) <u> </u> / <u> </u> / <u> </u>	1. Enter the result of most recent test taken <u>on</u> or <u>before</u> the certification date listed in Section A. Enter (a) arterial blood gas PO ₂ and/or (b) oxygen saturation test. Enter date of test (c).		
Y N	2. Was the test in Question 1 performed EITHER with the patient in a chronic stable state as an outpatient OR within <u>two</u> days prior to discharge from an inpatient facility to home?		
1 2 3	3. Circle the one number for the condition of the test in Question 1: (1) At Rest; (2) During Exercise; (3) During Sleep		
XXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXX	4. Physician/provider performing test in Question 1 (and, if applicable, Question 7). Print/type name and address below: NAME: _____ ADDRESS: _____		
Y N D	5. If you are ordering portable oxygen, is the patient mobile within the home? If you are <u>not</u> ordering portable oxygen, circle D.		
_____ LPM	6. Enter the highest oxygen flow rate ordered for this patient in liters per minute. If less than 1 LPM, enter a "X".		
a) <u> </u> mm Hg b) <u> </u> % c) <u> </u> / <u> </u> / <u> </u>	7. If greater than 4 LPM is prescribed, enter results of most recent test <u>taken on</u> <u>4</u> LPM. This may be an (a) arterial blood gas PO ₂ and/or (b) oxygen saturation test with patient in a chronic stable state. Enter date of test (c).		
IF PO₂ = 56-59 OR OXYGEN SATURATION = 89%, AT LEAST ONE OF THE FOLLOWING CRITERIA MUST BE MET.			
Y N D	8. Does the patient have dependent edema due to congestive heart failure?		
Y N D	9. Does the patient have cor pulmonale or pulmonary hypertension documented by P pulmonale on an EKG or by an echocardiogram, gated blood pool scan or direct pulmonary artery pressure measurement?		
Y N D	10. Does the patient have a hematocrit greater than 56%?		
NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):			
NAME: _____		TITLE: _____ EMPLOYER: _____	
SECTION C Narrative Description of Equipment and Cost			
(1) <u>Narrative</u> description of all items, accessories and options ordered; (2) Supplier's charge and (3) Medicare Fee Schedule Allowance for <u>each</u> item, accessory and option. (<i>See instructions on back.</i>)			
SECTION D Physician Attestation and Signature/Date			
I certify that I am the treating physician identified in Section A of this form. I have received Sections A, B and C of the Certificate of Medical Necessity (including charges for items ordered). Any statement on my letterhead attached hereto, has been reviewed and signed by me. I certify that the medical necessity information in Section B is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact in that section may subject me to civil or criminal liability.			
PHYSICIAN'S SIGNATURE _____		DATE <u> </u> / <u> </u> / <u> </u> (SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)	

SECTION A: (May be completed by the supplier)

CERTIFICATION TYPE/DATE: If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked "INITIAL," and also indicate the recertification date in the space marked "REVISED." If this is a recertification, indicate the initial date needed in the space marked "INITIAL," and also indicate the recertification date in the space marked "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.

PATIENT INFORMATION: Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on his/her Medicare card and on the claim form.

SUPPLIER INFORMATION: Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC).

PLACE OF SERVICE: Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.

FACILITY NAME: If the place of service is a facility, indicate the name and complete address of the facility.

HCPCS CODES: List all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification should not be listed on the CMN.

PATIENT DOB, HEIGHT, WEIGHT AND SEX: Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.

PHYSICIAN NAME, ADDRESS: Indicate the physician's name and complete mailing address.

UPIN: Accurately indicate the ordering physician's Unique Physician Identification Number (UPIN).

PHYSICIAN'S TELEPHONE NO: Indicate the telephone number where the physician can be contacted (preferably where records would be accessible pertaining to this patient) if more information is needed.

SECTION B: (May not be completed by the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed, and the CMN signed (in Section D) by the ordering physician.)

EST. LENGTH OF NEED: Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the physician expects that the patient will require the item for the duration of his/her life, then enter 99.

DIAGNOSIS CODES: In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 3 codes).

QUESTION SECTION: This section is used to gather clinical information to determine medical necessity. Answer each question which applies to the items ordered, circling "Y" for yes, "N" for no, "D" for does not apply, a number if this is offered as an answer option, or fill in the blank if other information is requested.

NAME OF PERSON ANSWERING SECTION B QUESTIONS: If a clinical professional other than the ordering physician (e.g., home health nurse, physical therapist, dietician) or a physician employee answers the questions of Section B, he/she must print his/her name, give his/her professional title and the name of his/her employer where indicated. If the physician is answering the questions, this space may be left blank.

SECTION C: (To be completed by the supplier)

NARRATIVE DESCRIPTION OF EQUIPMENT & COST: Supplier gives (1) a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; (2) the supplier's charge for each item, option, accessory, supply and drug; and (3) the Medicare fee schedule allowance for each item/option/accessory/supply/drug, if applicable.

SECTION D: (To be completed by the physician)

PHYSICIAN ATTESTATION: The physician's signature certifies (1) the CMN which he/she is reviewing includes Sections A, B, C and D; (2) the answers in Section B are correct; and (3) the self-identifying information in Section A is correct.

PHYSICIAN SIGNATURE AND DATE: After completion and/or review by the physician of Sections A, B and C, the physician must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0534. The time required to complete this information collection is estimated to average 10 minutes per response, including the time to review instructions, search existing resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: HCFA, P.O. Box 26684, Baltimore, Maryland 21207 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

HCFA inadvertently excluded mention and description of revision to HCFA-484 in **Federal Register** Notices announcing agency and OMB review of the currently pending OMB submission 0938-0679, "Durable Medical Equipment Regional Carrier, Certificate of Medical Necessity", Forms HCFA-841 through HCFA-853. While all oxygen CMN related public comments received thus far on 0938-0679 will be considered by DHHS and OMB during this emergency approval process, public comment related to this proposed collection are still encouraged.

To obtain copies of the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcf.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collection HCFA-484, OMB #0938-0534, should be sent 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: April 17, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97-10490 Filed 4-21-97; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of The HRSA Competitive Grants Preview

AGENCY: Health Resources and Services Administration.

ACTION: General Notice.

SUMMARY: HRSA announces the availability of the HRSA Competitive Grants Preview publication (hereinafter referred to as The Preview) which constitutes a description of the Agency's competitive grant programs for Fiscal Year 1997. The purpose of the Preview is to provide the general public with a single source of program and application information related to the Agency's annual grant review cycle. The Preview is designed to replace multiple **Federal Register** notices which traditionally advertised the availability

of HRSA discretionary funds for its various programs. The HRSA Preview will appear annually in the **Federal Register**. The Fiscal Year 1997 Preview appears as Attachment A to this notice.

Although the Preview describes the majority of HRSA discretionary grant program areas, it should be noted that other program initiatives, responsive to new or emerging issues in the health care area, and unanticipated at the time of publication of the Preview, may be advertised through the **Federal Register** mechanism from time-to-time. Some programs described in the initial Preview have appeared in **Federal Register** announcements earlier this Fiscal Year. Deadlines or other requirements appearing in the **Federal Register** are not changed by this notice.

The Preview will contain a description of all competitive programs and will include instructions on how to access the Agency for information and how to receive application kits upon availability. Specifically, the following information for each competitive grant program area will be provided: (1) Program Title; (2) Legislative Authority; (3) Purpose; (4) Eligibility; (5) Estimated Amount of competition; (6) Estimated number of awards; (7) Funding Priorities and/or Preferences; (8) Projected Award Date; (9) Application Deadline; (10) Application kit availability; and (11) The Catalog of Federal Domestic Assistance (CFDA) program identification number.

The first issue of the Preview relates exclusively to funding under HRSA discretionary authorities and programs as follows:

Primary Health Care Programs

- Community and Migrant Health Centers
- Health Care For The Homeless
- Grants to States for Loan Repayment Programs
- Ryan White Title III Planning Grants
- Grants to States for Community Scholarship Programs

Maternal and Child Health Programs

- Genetic Services
- Managed Care Policy and Children with Special Health Care Needs
- Integrated Services For Children With Special Needs
- Partnership for Information and Communications
- State Fetal and Infant Mortality Review Support Centers
- Health, Mental Health and Safety for Schools
- Partners in Program Planning for Adolescent Health

- Sudden Infant Death Syndrome (SIDS) and Other Infant Death (OID) Program Support Center
- Health And Safety in Child Care Settings
- Data Utilization and Enhancement For State/Community Infrastructure Building and Managed Care
- Healthy Tomorrows Partnership for Children
- Community Integrated Service Systems (CISS) Research Grants
- Maternal and Child Health Provider Partnership Cooperative Agreement
- Community Integrated Services Systems (CISS)—Local/State Community Organization Grants
- Maternal and Child Health Research Cycle
- Long Term Training In Adolescent Health
- Long Term Training In Behavioral Pediatrics
- Long Term Training In Communication Disorders
- Long Term Training In Pediatric Dentistry
- Long Term Training In Pediatric Occupational Therapy
- Long Term Training In Pediatric Physical Therapy
- Long Term Training In Public Health Social Work
- Continuing Education and Development
- Emergency Medical Services for Children: Implementation Grants
- Emergency Medical Services for Children: Planning Grants
- Emergency Medical Services for Children: Partnership Grants
- Emergency Medical Services for Children: Targeted Issues Grants
- Ryan White Title IV; Grants for Coordinated HIV Services and Access To Research for Children, Youth, Women and Families
- Healthy Start Cooperative Agreements
- Traumatic Brain Injury Demonstration Grants

Rural Health Programs

- Rural Outreach, Network Development Grant Program
- Telemedicine Network

ADDRESSES: Individuals may obtain the HRSA Preview by calling HRSA's toll free number, 1-888-333-HRSA. The HRSA Preview may also be accessed on the World Wide Web on the HRSA Home Page at: <http://www.hrsa.dhhs.gov/>.